IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	Hon. Dan A. Polster
	MDL No. 2804
THIS DOCUMENT APPLIES TO ALL CASES	No. 17-MD-2804

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HIGHLY CONFIDENTIAL -
SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

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THURSDAY, JANUARY 17, 2019

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Videotaped Deposition of ARTHUR F. MORELLI, held at the Law Offices of ROBBINS GELLER RUDMAN & DOWD LLP, 655 West Broadway Street, Suite 1900, San Diego, California, beginning at 9:10 a.m., before Sandra Bunch VanderPol, FAPR, RMR, CRR, CALIFORNIA CSR #3032

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APPEARANCES (Continued)

Also Present:

RYAN WONG, Videographer

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BE IT REMEMBERED that on Thursday, the 17th day of January, 2019, commencing at the hour of 9:10 a m. in the law offices of Robbins Geller Rudman & Dowd LLP, 655 West Broadway Street, Suite 1900, San Diego, California, before me, Sandra Bunch VanderPol, a Certified Shorthand Reporter in and for the State of California, personally appeared.

ARTHUR F. MORELLI,

called as a witness (Mallinckrodt), who, having been duly sworn, was thereupon examined and interrogated as hereinafter set forth.

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THE VIDEOGRAPHER: We are now on the record.

My name is Ryan Wong. I'm a videographer for Golkow Litigation Services. Today's date is January 17th, 2019, and the time is 9:10 a m.

This video deposition is being held in San Diego, California, in the matter of National Prescription Opiate Litigation, for the United States District Court, Northern District of Ohio.

The deponent is Art Morelli.

Will counsel please identify themselves for the record.

MR. SAMSON: Mark Samson, of Keller

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Rohrback, for the MDL plaintiffs.
MS. GAFFNEY: Alison Gaffney, of Keller Rohrback, also for the MDL plaintiffs.
MS. HERZFELD: Tricia Herzfeld, of Branstetter, Stranch & Jennings, for the Tennessee plaintiffs.
MR. GROSSMAN: Randy Grossman, Jones Day, on behalf of Walmart.
MR. DAVISON: William Davison, of Ropes & Gray, on behalf of Mallinckrodt LLC, Spec GX, LLC, and the witness.
MR. MAEROWITZ: Max Maerowitz, on behalf of the same defendants, of Ropes & Gray.
THE VIDEOGRAPHER: On the phone?
MR. SHAPLAND: Eric Shapland, on behalf of the Endo and Par entities.
MS. CALLAS: Gretchen Callas, with Jackson Kelly, on behalf of AmerisourceBergen.
MS. MOBLEY-RITTER: Devon Mobley-Ritter of Covington & Burling, on behalf of McKesson.
THE VIDEOGRAPHER: The court reporter is Sandy VanderPol, and she will now swear in the witness.
THE REPORTER: Raise your right hand, please.

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Do you solemnly swear or affirm that the testimony you are about to give in this proceeding will be the truth, the whole truth, and nothing but the truth, so help you God?
THE WITNESS: I do.
EXAMINATION
BY MR. SAMSON:
Q. Good morning, Mr. Morelli. Will you state your full name for the record, please.
A. Sure. Arthur, A-r-t-h-u-r, F. Morelli, M-o-r-e-l-l-i.
Q. I've seen 3rd next to it sometimes. Are you a 3rd?
A. I'm not a 3rd, no.
MR. SAMSON: Okay. I will ask you about that.
(Exhibit No. 1 was marked.)
BY MR. SAMSON:
Q. Let me show you what's been marked as Exhibit 1 to your deposition. Have you seen this before? It's the notice of deposition.
A. I have not, no.
Q. Okay. How many times have you been deposed before?
A. Once.

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Q. Okay. We will talk about that a little later.
Let's go over a couple of ground rules for depositions so that you and I can be sure we're on the same page; okay?
A. Okay.
Q. First of all, even though this is an informal setting, you're under the same oath, have the same obligation to testify fully and accurately and truthfully as if we were in front of a court; do you understand that?
A. I totally understand.
Q. Okay. You understand that what you say today can be -- will be taken down and put into a transcript form of your testimony, and that can be used in various ways throughout the lawsuit?
A. I understand, yes.
Q. Now, because of that, it's important that today isn't a bad day because of medication, personal stress, any other reason for you to pull up events from the past and tell us about them. Is today as good a day as any for that?
MR. DAVISON: Objection to form.
THE WITNESS: Today is a great day.
MR. SAMSON: I think I have seen on some of

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your emails.
Q. So one very important fact is when lawyers ask witnesses in different pursuits, like your own, questions, it may not come across to you as understandable. Do you understand you're not under any obligation to try and guess what I'm asking you, but only what you understand?
A. I understand that, yeah.
Q. Therefore, if you don't understand the question, I will ask you to ask me to rephrase it, ask me a question, "Do you mean X or Y?" And I will be happy to do that. Will you take that opportunity?
A. I will do that.
Q. Okay. And as a corollary, if you answer a question without being confused and bringing it up to me, is it fair to assume that you understood the question?
A. That's fair.
Q. And one thing we haven't gotten into, but you're doing pretty well, you haven't done the "uh-huh" and "uh-uh" yet for "yes" and "no." But just so the record is clear, unlike ordinary conversation, when it's an affirmative or a positive, no head shrugs or shoulder shrugs. Answer audibly;

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okay?
A. I will.
Q. If I correct you, I am not persecuting you. It's only to remind you to get back into this mode of communication instead of what we all do every day.
A. I understand.
Q. You can take a rest. It's not an endurance contest. Please just ask me, and we will take a break. The only corollary to that is if a question is pending, please answer that question and then say, "I'd like to take a break." Okay?
A. Okay.
Q. Throw-away question. Have you ever been arrested or convicted of a felony?
A. I have not.
Q. Turn to page 4 of Exhibit 1.
A. Okay.
Q. And even though you didn't see this, you see that there were -- there's a section about requests for documents to be produced?
A. Yes.
Q. Okay. And the first one is a copy of your current résumé or curriculum vitae.
A. Yes.

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Q. I received that this morning. So I take it --
A. Oh.
Q. -- you did produce that to counsel?
A. I sent it to counsel.
Q. And then if you turn to the next page, request for production No. 2 are:
(Reading) All documents, including electronic data and email, in your possession related in any way to any defendants, manufacturer, marketing, sale, distribution, suspicious order monitoring and lobbying efforts, in connection with its opioid business (end of reading).
Did you look through your personal documents to make sure you didn't have any responsive documents to that request?
A. I didn't, no.
THE VIDEOGRAPHER: Sorry, Counsel. I think my Elmo is not working right now. Do you mind if we go off the record to fix it real quick?
MR. SAMSON: No.
THE VIDEOGRAPHER: We are going off the record. The time is 9:17 a.m.

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(Off the record.)
THE VIDEOGRAPHER: We are back on the record. The time is 9:23 a m.
BY MR. SAMSON:
Q. Since you hadn't seen Request No. 2, I take it you have not made a search for any documents that might be responsive?
A. I have not.
Q. Let me ask you to go ahead and look through whatever memorabilia you have, and this would include emails on other servers that you've had with anyone at Mallinckrodt or any of the other manufacturers of opioids, reminisces you may have written to sort of catalog your time in that area, or anything else, and present them to William, your counsel.
A. Okay.
Q. And then he will see about getting them on to us; okay?
A. Okay.
Q. Look at No. 3:
(Reading) All documents you have consulted or reviewed or plan to consult in preparation for your deposition and on which you will rely

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in any way during your deposition (end of reading).
Are there any such documents responsive to that request?
A. I don't understand this. Is this a question? I don't think it's grammatically correct. I don't understand what you're asking me.
Have I looked at documents? Has counsel given me documents to look at?
Q. That's one way.
A. Oh, yeah.
Q. But since this is your personal documents --
A. Oh.
Q. -- did you look through any box of old things at home and found documents and looked them over to prepare for your deposition?
A. I looked at --
MR. DAVISON: Objection.
THE WITNESS: I looked at a few that I had just to refresh my memory, because I haven't been in this opioid space now for a couple of years.
BY MR. SAMSON:
Q. Okay. And it looks to me, from the records we received, that you left at the end of

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2011, Mallinckrodt at least?
A. Correct.
Q. And have you been in the opioid space in any professional endeavor since then?
A. I have.
Q. Okay. We will talk about that later.
A. Okay.
Q. Again, if there's anything that you have privately, that you looked into to prepare for your deposition today, please go ahead and give it to William. Make a copy of it --
A. Okay.
Q. -- and give it to him.
You started to say that there might have been something?
A. Just -- just to refresh my -- my memory and my -- kind of refresh what I had done in terms of names, dates, places, projects, just kind of very high level to reorient myself back into what you're interested in finding out.
Q. Okay. And what documents did you have at home that helped that process?
A. Slide -- slide decks, compendia reports that I receive from RADARS and other organizations that track, you know, opioid use.

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Materials that I created for other clients that are in the opioid space, just to kind of reorient myself and -- because I'm not working in the opioid space, and I haven't for a couple of years now. Yeah.
Q. When was the last time you worked in the opioid space?
A. Let's see. I would say approximately 2013, '14 range.
Q. And what were you doing in the 2013, '14 range that was in the opioid space?
A. I was consulting with companies who were bringing out opioid products to market and were interested in programs that would support the safe and effective use of those products or -- and/or helping them create a REMS that they think may have been required, the FDA would require for those products.
Q. And which were those companies?
A. Zogenics was one.
Q. And what was Zogenics producing in the opioid space?
A. They had immediate-release hydrocodone, analgesic single entity for chronic pain.
Q. A generic?

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A. No. A branded product.
Q. What was the brand name?
A. Zohydro.
Q. And who else?
A. Xcellerex.
Q. And is that a stand-alone company or --
A. That's a stand-alone company.
Q. And what was their product in the opioid space?
A. Yeah. Their product was a combined device, drug, sufentanil, a sublingual tablet being developed for pain associated with medical procedures, but only used in a structured setting like a hospital or a clinic, medically supervised setting, not -- not a prescription drug given to patients to take home.
Q. And, in your opinion, based on your experience in the industry, that setting, in a hospital I'm assuming it is --
A. Hospital or clinic.
Q. -- hospital or clinic with direct observation of dose taking, is that less of a risk for abuse, diversion, and some of the other problems with the opiates --

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MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. -- than --
MR. DAVISON: Sorry.
BY MR. SAMSON:
Q. -- drugs given out to patients who then take them on their own away from a clinic or hospital setting?
MR. DAVISON: Objection to form.
THE WITNESS: I would say the risks are different. And the operationalization of the product is very different. The distribution is less broad. There's other -- there's many differences.
One of the key ones is the distribution and availability is less broad. So in that sense, it helps mitigate risk. But there are other risks still associated. It's a very, very potent opioid, sufentanil. It's like ten to a hundred times more potent than fentanyl. It is very potent.
BY MR. SAMSON:
Q. And then any other companies?
A. Yes. Sentynl Pharmaceuticals.
Q. Like the person on watch?
A. Y-L, Y-L at the end, yeah.
Q. Okay. And what was their product?

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A. They had two opioid products. One a drug -- a fentanyl-based agent for breakthrough pain, which I was not involved with. And another oral agent for severe -- moderately severe to severe pain that I was involved with. But my involvement with Sentynl was very, very brief, and I resigned that account.

Q. Okay. Did you have a difference of opinion about how to approach the opioid space from Sentynl's managing team?

A. Yes, I did.

Q. Okay. And what was that difference of opinion?

A. That difference of opinion was, in my perspective was, they were not serious about implementing the safe use kinds of measures that I was recommending. And I have no tolerance for just makeshift or make it look good but there's nothing underneath it kind of approach.

Q. Was it your suspicion in dealing with Sentynl that they were more interested in selling the product than assuring the safety of the product?

A. Yes.

MR. DAVISON: Objection to form.

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BY MR. SAMSON:

Q. And that is unacceptable to you in any manufacturer, distributor, or seller in the opioid space?

A. Yes.

MR. DAVISON: Objection to form.

BY MR. SAMSON:

Q. What year was Zogenics, if you recall?

A. So kind of the sequence here. It was Xcellerex, Sentynl, and then Zogenics.

Q. Okay. In --

A. More or less in the '12, '13, '14 kind of range.

Q. I don't want to put words in your mouth. A year with each --

A. No.

Q. -- or shorter period with each?

A. Quite long with Zogenics, medium with Xcellerex, very short with Sentynl.

Q. Okay. Any -- any of the documents that you refreshed your recollection with, do you recall them specifically enough to describe them to me?

MR. DAVISON: Objection. And to the extent

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it's documents that were provided by us to you, I'm going to instruct you not to answer.

MR. SAMSON: That's -- that's good.

Q. You -- don't tell me the source. But if you recall an email of "X" date, you can tell me that's something that you looked at to refresh your recollection.

MR. DAVISON: And I'm going to instruct you not to answer if it's a document that I provided to you. That's the work -- protected by the work product document.

If you recall specific documents that you looked at on your own or your own documents, you can share those documents with him.

BY MR. SAMSON:

Q. Are you going to follow the instruction not to answer that part of it? I need to ask you that for the record.

And then tell me about the ones that did not come from counsel that you recall looking at.

A. So a general description of a box and stick map that I created to basically help people understand where -- how it works in a patient management setting with a physician dealing with -- potentially with patients and nonpatients, in terms

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of mitigating things like diversion, abuse, misuse, overdose, and addiction.

Q. Is -- is the map literally a map? A one page from a slide show? Or is it a presentation that shows how that system works?

A. It's a one-page descriptive box and stick map from -- from a slide deck that, you know, I -- I spoke to them, you know, for 30, 40 minutes on just that one slide to make sure they understood.

Q. And was that for Zogenics or Xcellerex or Sentynl or all three?

A. It was for Zogenics.

Q. Okay. I take it that that slide show still exists in your possession?

A. Not sure. Not sure.

Q. Well, the --

A. But that slide exists, I know that.

Q. Okay. Well, find whatever slides exist and provide them to William; okay?

A. Okay.

Q. Any other specific documents not given to you by counsel that you recall reviewing to get back into the opioid space for your deposition today?

A. I would say that would be the

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stand-out one that I -- that I recall that I went through.
Q. Was that box and stick of map mitigation ever used at Mallinckrodt when you were there?
A. Not that I recall.
Q. Okay. Let me get back to, you told me you had been deposed one other time.
A. Uh-huh.
Q. When was that?
A. It was approximately the year 2000, 2001.
Q. And what did that -- why did you come to be deposed?
A. Say that --
Q. Why did you come to be in a deposition.
A. Oh. It was concerning a lawsuit about a company that I co-founded in the area of bochalinum toxins, and it was about patent rights.
Q. And that would have been Solstice?
A. Solstice. Related to Solstice's product, yes.
Q. And Solstice was, as you said, bochalinum toxin?

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A. Type B.
Q. So did opiates come up in that deposition?
A. No.
Q. What's your current work address?
A. 5324 Ruette De Mer, San Diego, California, 92130.
Q. And who is your employer?
A. Enlyton, E-n-l-y-t-o-n, Limited is one employer. Another one is the Ohio State University Cancer Center, specifically the Drug Development Institute, the DDI, in Columbus, Ohio.
Q. And I take it from your earlier answers about opioid -- or opiate -- yeah, opioid involvement, the OSU Cancer Center is not for analgesia for cancer, but rather for actual treatment for the underlying condition?
A. Correct.
Q. And what about Enlyton, same thing? No -- no opioid or analgesic effect, but simply projects that come up for whatever the medicines involved are?
A. Correct.
Q. I saw -- let me show you, so you see the same thing I see.

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(Exhibit No. 2 was marked.)
BY MR. SAMSON:
Q. This is Exhibit 2 to your deposition. And that's just me Googling you.
A. Oh, yeah. Okay.
Q. From LinkedIn. And then another hit was with some outfit called Provident Partners.
A. Yes.
Q. What is Provident Partners?
A. Provident Partners is a Connecticut-based investment -- a company that looks for investments in the -- in the energy, gas, water area. And I'm an investor in Provident Partners, a small investor.
Q. And this had you on its page -- and I'm sorry I didn't copy it -- but as, "Art Morelli, expert in pharmaceutical finance."
Does Provident Partners do anything with any kind of pharmaceuticals?
A. Not today. But when I originally invested, they were interested in a pharmaceutical opportunity that helped patients comply and adhere to their medication schedules. But that didn't matriculate. So it's not existing anymore.
Q. Was that the light or the beeper on

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top of the bottles?
A. It was much more sophisticated than that, but it's the same concept, yeah.
Q. And are you still involved with Provident Partners?
A. Only as an investor.
Q. Okay. What was your last date at Mallinckrodt or Covidien? I will use Mallinckrodt, but I mean, in your instance, based on where you were working, Covidien?
A. I think in 2011. Somewhere in the year of 2011.
Q. I will go over some documents later. But if you will trust my memory.
A. Okay.
Q. There's a document in mid November where you are telling your team, here's what we need to do from -- for the rest of the year --
A. Okay.
Q. -- and now here's what we are going to do. And it was Exalgo-based in the next, you know, January through March.
And then I saw an email saying, not good-bye, Art, but we loved seeing you, being with you, like in late December. Does that give you any

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guidance?
MR. DAVISON: Objection to form.
THE WITNESS: I -- it doesn't really, no.
MR. SAMSON: Okay.
THE WITNESS: But I'm sure if you say it happened, it happened. But I don't recall that.
BY MR. SAMSON:
Q. But would the end of 2011, early 2012 be -- fit your memory of when you last worked there?
A. It sounds about right. Yeah.
Q. Okay. Did you meet with counsel for Mallinckrodt to prepare for your deposition today?
A. I did.
Q. Okay. How many times?
A. Twice.
Q. And were those phone or in person?
A. In person.
Q. Here in San Diego?
A. Yes.
Q. And how long was the first meeting?
A. About a day.
Q. And I trust you were shown documents at it?
A. I was.
Q. And then when was the second meeting?

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A. Yesterday.
Q. And in terms of timing, how long ago was the first meeting?
A. Mid December.
Q. And when you say "a day," an eight-hour session with counsel?
A. Approximately, yes.
Q. And then yesterday, how long did you meet?
A. About a day.
Q. Another eight hours?
A. Another eight hours, yes.
Q. Were there any documents that you were shown in that, that refreshed your independent recollection of events back in the time frame?
A. Yes.
Q. Which ones?
MR. DAVISON: Objection. The documents that we showed to Art are protected by the work product.
I'm not going to -- I'm going to instruct you not to answer as to specific documents. If you want to give him high-level categories, I will allow that.
MR. SAMSON: We will have that battle later.
THE WITNESS: Okay.

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BY MR. SAMSON:
Q. But are you going to follow that instruction of your counsel?
A. Absolutely. So the high level is, I was shown a series of emails, some of which, you know -- a series of email strings, some of which I had an email within the string, some of which I didn't. Some documents that we created as part of the C.A.R.E.S. Alliance. And that's -- that's basically it.
Q. Other than counsel, in the time since you left Mallinckrodt, have you met or spoken with anyone about your time at Mallinckrodt?
A. No.
MR. SAMSON: Okay. Now, you've got 2 in front of you. Let me give you 2-A.
(Exhibit No. 2-A was marked.)
BY MR. SAMSON:
Q. And this is a résumé that we received today.
A. Okay.
Q. And is this something you did yourself, I take it?
A. I think someone did it for me, actually.

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Q. But it's current to the present?
A. It's current, yes.
Q. Okay. And both of these, 2 and 2-A, show that your degree was a B.A. in biology from Wabash College?
A. Correct.
Q. What year?
A. 1969.
Q. And since a B.S. in biology usually doesn't involve opioids, am I safe in saying that that wasn't a focus of your education at Wabash?
A. It was just a biology major and chemistry minor. So it was heavy in science.
Q. Okay. And then on 2-A, your résumé, you say you did a business seminar for pharmaceutical executives at UCLA Business School, Los Angeles, California.
When was that?
A. That would have been in the early '90s.
Q. Okay. And a seminar can extend from a one-hour/one-day event to some sort of a longer-lasting program. Which was this?
A. They -- they were different. The UCLA program was a two-day program.

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Q. Okay. And taught at UCLA?
A. Yes. Yes.
Q. And in the early '90s, did it have any focus on opioids?
A. It did not.
Q. And was it -- since it was for pharmaceutical executives and also has business in the title, was it more on the business end of pharmaceutical industry?
A. It was more on the analytical, on the analytical aspects of pharmaceutical company operations.
Q. How one finds out if you're spending more to produce the product that you're selling --
A. No.
Q. -- and that sort of thing?
A. No. It wasn't so much economics based. It was analytics related to product development, product uptake, assessment of product success, those kinds of things.
Q. And then there's another, "Managing Global Opportunities, U.S. and China," at the Harvard Business School, a resident executive program. When did you take that?
A. That was in the mid '90s.

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Q. And, again, any focus or even mention of opioids in that program?
A. No.
Q. And, again, length of time? Is that a whole semester or a day, two days?
A. This was about a three-to-four-week course that was taught at the Harvard -- in the Harvard Business School and also in China.
Q. And was the focus on pharmaceutical -- when you hear China, you always think of American companies thinking of opening markets to the Chinese.
A. Uh-huh.
Q. Was that a focus of the program?
A. It was --
MR. DAVISON: Objection to form.
THE WITNESS: It was part of the focus. It was how to -- how to operate, you know, either as a company, a pharma company in China or in an export relationship with a local partner in China.
BY MR. SAMSON:
Q. And it was pharmaceutical based, though?
A. It was pharmaceutical based.
Q. And I may have asked you this. No

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opioid focus?
A. No.
Q. And then I have seen your "Science-Based Approach to Risk Management" poster at Pain Week Meeting in 2010. And that would have been the founding event of C.A.R.E.S.? Did that come out in conjunction with it?
A. It was --
MR. DAVISON: Objection to form.
THE WITNESS: It was part of the prework, predevelopment work for which tools would be appropriate for inclusion into the C.A.R.E.S. Alliance.
MR. SAMSON: And, Ms. Court reporter, C.A.R.E.S. is C, period, A, period, R, period, caps, E, period, and then a small "S"?
THE WITNESS: Big "S."
MR. SAMSON: Big "S," period, and then Alliance.
Q. When I used that term, since you picked it up that time without much trouble, I take it that will be -- if I say C.A.R.E.S., you will know I'm talking about the C.A.R.E.S. Alliance?
A. I will.
Q. All right. Now, let's go to your

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work background, which I think tracks pretty well between Exhibit 2, the LinkedIn, and 2-A, the résumé. And both start with DuPont Pharmaceuticals in Wilmington, Delaware.
A. Right.
Q. What were the drugs, the pharmaceuticals that DuPont was selling in those days?
A. DuPont had a -- quite a broad range of different products, from Coumadin, which you may have heard of, which is for blood clots; Symmetrel you may not have heard of, for influenza A and Parkin- -- Parkinsonian-like syndromes that people can sometimes get; Percocet, which you've probably heard of, which is an opioid, acetaminophen analgesic compound; Percodan, you may not have heard of that, but that's an oxycodone/aspirin combination.
And there were a few others, cough/cold type products, but those were the main products that I started with and cut my teeth on as an entry level position into the pharmaceutical industry.
Q. Okay. And were you ever a detailer?
A. I was.
Q. Going out to physician offices?
A. I did. That's how I started.

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Q. And in that detailing work, did you handle Percocet and Percodan?
A. I did.
Q. And the detailing side of marketing and/or sales, however the company divides it, is talking to the doctors and encouraging them to write prescriptions for your company's products?
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. True?
A. It is. It's carrying a bag of samples on the south side of Chicago. That's how I started. Okay. And talking to doctors. If you want a picture in your mind.
Q. Got it. But --
A. But no samples of Percocet.
Q. You don't strike me as an imprudent gentleman.
A. Thank you.
Q. So that does not surprise me.
But, basically, if you were -- were you not selling Percodan and Percocet at the start on the south side?
A. I was. I was. I was talking to doctors about those products, among other products.

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Q. And explaining to them, here are the uses of them, here is why they are better than competitive product?
MR. DAVISON: Objection to form.
THE WITNESS: Not so much why they are better from competitive products, but what the indication was, what the dose is, what the data supporting those products are. Because there were no direct comparisons that we had, so we had to work with what was the FDA-approved package insert.
BY MR. SAMSON:
Q. Okay. And that stayed true the whole time you were in the opioid space, was the package insert for indications is a line you can't cross in the detailing and marketing world?
A. It is.
Q. And then so, I take it, did you start sometime earlier than 1990, then?
A. I did. I started -- I started in 1990, actually -- I'm sorry. I started in 1980. Yeah.
Q. Okay.
A. I didn't put it all on here because it was too many pages. Yeah.
Q. And how long were you in either that

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direct detailing end of things or still within pretty much ordinary marketing of existing product?
MR. DAVISON: Objection to form.
THE WITNESS: So I was in that direct detailing, that you described, for one to two years. Then I was promoted to being a Hospital Representative, also in Chicago. And I was a Hospital Representative for three-ish -- three-ish kind of years.
And then I became a District Manager in -- in Houston, Texas for a few years. Then I became a District Manager of Hospital Representatives in South Florida for one year. And then that picks up with Director, Emerging Markets there in 1990. I was then promoted into the home office for an international sales and marketing position.
BY MR. SAMSON:
Q. And in the hospital district manager position in Florida, that would have been '89, roughly?
A. Roughly, yeah.
Q. And what does a hospital-based program rather than detailing at individual physicians' offices or clinics, what's the difference between those two?

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A. So my team of sales representatives visited institutions rather than doctors in their offices and had -- did presentations and had discussions with physicians who had a hospital-based practice or were, you know, anesthesiologists who operate -- you know, were in the operating room or surgeons who were based in the operating room, rather than family practice or general practice physicians who were mainly office space.
Q. And in 1989 in Florida, when you were a DM of the hospital services, did you cover all of Florida?
A. Oh, I covered more than Florida. Florida, parts of Georgia, parts of South Carolina. Yeah.
Q. In your time there, was there a perception of an opioid epidemic in Florida and the surrounding states?
A. There was not.
MR. DAVISON: Objection to form.
THE WITNESS: There was not.
BY MR. SAMSON:
Q. And at that time, since you would have been familiar from your detailing work, was the general rule of prescription of opioids per need?

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MR. DAVISON: Objection to form.
THE WITNESS: Are you talking about dosing, p.r.n. dosing --
MR. SAMSON: Yes.
THE WITNESS: -- is that what you're asking me?
MR. SAMSON: Uh-huh.
THE WITNESS: By some physicians, yes. Not all.
BY MR. SAMSON:
Q. Okay. And in the per-need era, there was amongst physicians a fairly -- strike that.
Amongst physicians in that per-need period, wasn't it true that physicians were reluctant to prescribe opiates?
MR. DAVISON: Objection to form.
THE WITNESS: I can't comment on what all physicians may have been thinking. But what I can say is that p.r.n. dosing was often practiced by the physicians that I spoke with, but not universally practiced, as opposed to time-contingent dosing.
BY MR. SAMSON:
Q. And one of the effects of per-need dosing in general versus time contingent, is that in the per-need model, there will generally be less

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milligrams of active molecule going to a patient in a given period than when they are on it regular dose; true?
MR. DAVISON: Objection to form.
THE WITNESS: Not necessarily true. Not necessarily true. In an individual case, it could be true or not true.
BY MR. SAMSON:
Q. Okay. And why did you leave -- were -- when you were in emerging markets --
A. Yes.
Q. -- was that Percodan and Percocet --
A. No.
Q. -- or something else?
A. Nonopioid products. All of our nonopioid products.
Q. Okay. And how about when you were Director of New Product Planning, was that opioid related or nonopioid?
A. Nonopioid.
Q. And then when you were Senior Director of Marketing, was that opioid or nonopioid?
A. Nonopioid.
Q. Okay. Had Percocet and Percodan gone elsewhere by then, or director of marketing just

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didn't do anything with them?
A. It was a senior -- a Senior Director of Marketing for the launch of a new product that I was focused on. Percodan and Percocet were still there, still products of the company, but I wasn't involved with them.
Q. And what was the new product?
A. The new product was a drug for HIV, Sustiva. First. And then it was a low molecular weight heparin product for management of thrombosis.
Q. Anticoagulation?
A. Correct.
Q. Okay. And then you went to Cardinal Health here in San Diego?
A. That's right.
Q. In 2000?
A. Right.
Q. And what did you do after Cardinal Health?
A. So I was recruited to -- to join Cardinal Health after 20 years at DuPont. And Cardinal was developing a new business model to partner up with Nascent, an emerging pharma and biotech company, especially on the West Coast, in my case. And Cardinal wanted to become more than just a

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drug distributor at that time. They wanted to become a more integrated partner to provide other services to the pharma industry, which would include, as it says there, manufacturing unique dosage forms, sales initiatives, marketing programs, et cetera. So that was my job, to establish relationship with these various companies.
Q. Okay. And would that lead -- was the hope that Cardinal, through a relationship, would have a direct relationship with new drug company that -- or new technology that came out and have a favored position?
MR. DAVISON: Objection to form.
THE WITNESS: I'm not sure about a favored position. I would say it's a more -- more broad and in-depth relationship. You might say it is cross selling. Yeah.
BY MR. SAMSON:
Q. Okay. Was Cardinal distributing opioids when you were there from 2000 to 2002?
A. I assume, yes. But I wasn't involved in the drug distribution part of Cardinal.
Q. And so from your -- from what you learned about opioids and how they were being used, et cetera, did you gain any knowledge from -- at

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Cardinal from 2000 to 2002?
MR. DAVISON: Objection to form.
THE WITNESS: I gained knowledge, yeah.
BY MR. SAMSON:
Q. And what was the knowledge you gained during that time frame?
A. Knowledge about all Cardinal's lines of business. But the one -- Cardinal's biggest line of business, the one I was least involved with, is the distribution business, a big distribution business. There's one other subcategory of distribution that I was involved with, and that's called third-party logistics. That's a subset of generalized drug distribution.
Q. And what does that subset deal with?
A. It deals with companies that are small, emerging, that really aren't in a position to establish a warehouse and distribution mechanism of their own, so they -- they ask Cardinal to do it on their behalf. So Cardinal has a large warehouse where they act as the company's warehouse and distribution point.
Q. Okay.
A. Yeah.
Q. And when you say "small companies,"

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small company's distributors or small company's manufacturers, producers?
A. Manufacturers, yeah.
Q. And did you, in your time at DuPont Pharmaceuticals, have anything to do with suspicious order monitoring or order tracking, antidiversion?
A. No.
Q. Then you went to Elan Biopharmaceuticals? And where was that?
A. Here in San Diego.
Q. And was that a startup?
A. No.
Q. Okay. It was established?
A. Established.
Q. Okay. And you oversaw worldwide operations, planning, for two lead pipeline products; correct?
A. Correct.
Q. And one was Tysabri. And is that multiple sclerosis?
A. That is multiple sclerosis.
Q. And also a drug called Prialt in pain?
A. Right.
Q. What was Prialt's active molecule?

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A. Prialt was -- you're stumping me now. I don't remember. But it was a small peptide injected through an implantable pump into chronic pain patients. It was a nonopioid adjunctive agent to their pain management.
Q. Do you recall, what was the risk profile of Prialt?
MR. DAVISON: Objection to form.
THE WITNESS: Again, it's nonopioid. So it didn't have the opioid profile. But it had certain CNS side effects that frequently cropped up but were manageable by better dosing, low dosing. It was a very, very low-dose drug. It has to be accurately dosed. That's why that implantable intravenous pump is the approach that -- that's used.
BY MR. SAMSON:
Q. When -- I think when you were in Mallinckrodt, but perhaps I'm wrong, they had an intrathecal pump system; true?
MR. DAVISON: Objection.
THE WITNESS: Mallinckrodt. I believe they did, actually.
BY MR. SAMSON:
Q. And was that opioid --
A. It was nonopioid.

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Q. -- in that instance?
That was a nonopioid?
A. I believe it was nonopioid, yeah.
Q. And in terms of the planning on the campaign for -- had Prialt been launched before you got there, or were you involved in the launch? Since it says "planning," it confuses me.
A. I'm pretty sure I was involved in the launch, yeah. I definitely was involved in the launch of Tysabri.
Q. Okay. And Tysabri, whatever great effects it has on slowing the progression of multiple sclerosis, it doesn't have anything to do with pain, isn't used for pain?
A. It's not indicated for pain. Only indirectly, if it would relieve symptoms. But, no, it's not -- it's not an indicated analgesic.
Q. And in terms of launching Prialt, was one of the features that you and Elan Biopharmaceuticals presented to the target audience, was that it was a nonopioid, so it didn't have the opioid risks?
A. Absolutely. And it was opioid sparing. This is when -- the very beginning of the opioid-sparing concept.

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Q. And describe opioid sparing for me in your terms?
A. So to achieve -- achieve the goal of therapy, which is analgesia, simplistically, you could have two approaches. One, dose opioids till you reached analgesia; or, two, dose opioids plus an adjunctive agent to reach analgesia with a lower total dose of the opioid, which is always a goal of therapy with opioids, is to achieve the goal of therapy at the lowest possible dose.
Q. And the thinking was at Elan, that Prialt might be a stand-alone treatment, but certainly if used with opioids, it would cause the patient to need less opioids?
A. Yes.
MR. DAVISON: Objection.
BY MR. SAMSON:
Q. And have you ever, in any of your contacts with the opioid and pain space, found a scientifically-supported idea that you believe in that promotes the fact that somehow more opioids are better --
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. -- for a patient?

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MR. DAVISON: Sorry.
THE WITNESS: So unbridled, unbridled, unlimited, more opioids are always better, is not anything that anybody believes in today or really practices today, as far as I know.
BY MR. SAMSON:
Q. At some point was there such a belief?
MR. DAVISON: Objection to form.
THE WITNESS: I don't really know what all physicians did. But it was more -- you might say it was more common, based on the state of knowledge at one point.
BY MR. SAMSON:
Q. And when was that point?
A. I can't recall exact. But there's been a shift in the thinking over -- over decades, quite frankly. A couple decades, yeah.
Q. Well, when you were in the 1990s, we were talking about per-need dosing --
A. Right.
Q. -- which -- and you said you couldn't answer for all physicians, but physicians were a bit leery of opioid usage for pain; true?
MR. DAVISON: Objection to form.

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THE WITNESS: I would say that physicians are clearly concerned about the safety of their patients, number one. The FDA mandate is safety, number one.
So all the responsible people, all the adults in the room, put patient safety first. And if it's good enough for the FDA, it's good enough for me.
BY MR. SAMSON:
Q. Okay. And you didn't notice from the '90s through when you left Mallinckrodt, that, in general, a lot more opioids were being used in the pain space?
MR. DAVISON: Objection to form.
THE WITNESS: I don't have the data. But my -- my -- my belief is, yes.
BY MR. SAMSON:
Q. So something was moving the medical market, physicians, prescribers, because nobody can get an opioid without a prescriber writing a script for it; true?
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. Before and after --
A. Legally, yes.

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Q. So that's not -- well taken.
A. Yeah, the -- what was -- I will wait for you to ask the next question.
Q. Sure. But at some point the reluctance to prescribe opiates decreased; true?
MR. DAVISON: Objection to form.
THE WITNESS: I'm not sure. Perhaps. But I wouldn't characterize it that way.
BY MR. SAMSON:
Q. How would you characterize it?
A. I would characterize it as the -- there was more of a recognition of patient pain, chronic pain. Patient chronic pain was becoming more the incidence, and prevalence of chronic pain was increasing.
You have got to remember, we're talking about a fairly long period of time. So you have an aging population. You have people with greater incidence and a better understanding of the diagnosis of chronic pain, and patients presenting to physicians with the diagnosis of chronic pain. That pain is debilitating. That pain is crushing to those patients. And physicians are going to meet the needs of their patients, but in the context of safe provision of therapy.

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Q. And do you believe that in, say, 2006 till you left in 2000- -- left Mallinckrodt in the end of 2011, the balance had swung to where too many opioids were being used, regardless of the underlying pain?

MR. DAVISON: Objection to form.

THE WITNESS: Maybe in some cases. I don't really know. But I can tell you this. That during the period that you -- the time period that you identified, I, quite frankly, didn't follow what the sales were, nor did I care.

What I cared about is whatever prescriptions, opioid prescriptions that physicians were going to write, that they were done in the safest, most conservative possible way, and that patients were treated -- their pain was treated holistically, not papering over their problems with more and more opioids.

Because, remember, pain is not a disease. It's a symptom. And it's a very potent symptom for a patient to have to deal with, when you consider disability, activities of daily living, their ability to work, go to school, et cetera, et cetera. So to be able to put these patients in a -- in a better situation where they can function in life without

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being debilitated by their pain or debilitated by their opioid. So it takes a very holistic, systematic approach for physicians to be able to provide that type of therapy. It goes beyond just writing more prescriptions.

BY MR. SAMSON:

Q. Say I agree with you in terms of that perfect system that you described. For some reason there were more and more opioid prescriptions being written in that 200- -- 2000, early 2000s to the time you left Mallinckrodt; true?

MR. DAVISON: Objection to form.

THE WITNESS: I don't doubt it. But I don't have the data. I don't doubt it.

BY MR. SAMSON:

Q. Okay. Now let's move us to Solstice Neuroscience in San Francisco. This is the Botulinum Type B?

A. It is.

Q. And you were a co-founder?

A. I was.

Q. And from 2004 to 2009, I'm assuming you were not in the pain space?

A. I was not.

Q. And was the Botulinum -- Botulinum

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Toxin in play here being used for plastic surgery effects or some deeper medical problems, or both?

A. Deeper medical problems, not -- not facial cosmetics.

Q. Okay. And what was the -- what was Myobloc being developed for or imported to treat?

A. A condition called cervical dystonia, which is a contraction of muscles on one side of the neck that causes patients to have their head in a tilted position, and is very, very painful.

Q. And since Botulinum is a -- actually a muscle effective drug, putting it in would break the cycle?

A. That's the -- that's the intent, yes.

Q. Okay.

A. It's a paralytic agent, actually.

Q. And so I'm confused. Was it -- was a cervical dystonia patient having constant contraction of one side or the other of their cervical musculature?

A. Yes. They would have an asymmetric contraction of neck muscles on one side. They would walk around like this, in excruciating pain. So you would -- the physician would inject those muscles with -- with bochalinum toxin, the muscles would

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gradually relax, and the patient's head would come back to a more neutral position, close to if not completely neutral. And then the toxin wears off in about 12 weeks, so the patient's condition would return. They would have to go back in for another injection. And they get cycled like that.

Q. And is the pain simply from the release -- or the pain relief simply from the release of the contract -- constantly contracted muscles?

A. I believe so.

Q. As you guys understood it?

A. As we understood it, yes.

Q. Okay. And then that lasted till 2009. What ended the Solstice Neurosciences chapter of Art Morelli's life?

A. I founded the company. I got the commercial operations of the company going. I raised the money to -- I raised over $40 million of venture capital money to get the company started. That product was a spin-out of Elan.

So I figured I had done my work. I had no further interest in working with the venture capitalists that funded our company. And so I left the company, and then I joined -- I joined Mallinckrodt --

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Q. Did that --
A. Cov- --
Q. I'm sorry. Go ahead.
A. Covidien.
Q. The fact that your other deposition in life was about, I'm assuming, something to do with the stock, the trademarks, whatever it is, of Solstice, tells me something didn't go all that happily as -- after you left or at the time you were leaving?
A. My --
MR. DAVISON: Objection to form.
THE WITNESS: -- resignation had nothing to do with the deposition.
BY MR. SAMSON:
Q. Okay. And then you were simply a fact witness to -- why were you at the deposition?
A. I don't really know. But I -- it was about the intellectual property rights. That's what I remember.
Q. Did you have an interest in the intellectual property rights either asserted or actual?
A. Yes. Because I was a stockholder in the company.

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Q. Okay. And were you a plaintiff in that suit that you got deposed in?
A. A defendant.
Q. A defendant?
A. Yeah.
Q. And what was the end result?
A. It didn't resolve while I was there. But subsequently I believe it resolved amicably in some way. But I don't know the details.
Q. Okay. All right. So how did you come to be hired by Covidien, slash, Mallinckrodt?
A. I was recruited by the CEO at the time.
Q. Who was the CEO?
A. Tim Wright.
Q. How does he spell his name?
A. W-r-i-g-h-t.
Q. And did you and Mr. Wright have past dealings?
A. We did. We worked at a couple companies together.
Q. A couple of the ones we've gone through?
A. Yes.
Q. Which ones?

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A. DuPont and Cardinal Health.
Q. And did you approach Mr. Wright since you were getting out of Solstice, or did Mr. Wright approach you?
A. I approached him.
Q. And did you come to him with a -- some Covidien-specific vision or simply, I'm no longer working here; do you have a spot for me?
A. I would say it's somewhere in between. I came to him with a -- you know, proposed that added to the senior management team, I would add value to the company in a potential variety of ways.
Q. Okay.
A. Yeah.
Q. Give me the variety of ways that you would have told Mr. Wright you saw as potential advantages to Covidien taking you on.
A. Marketing. Operations. Improvement in efficiencies. That type of thing.
Q. Okay. And for a non-businessman like me, marketing is devising strategies and tools to increase a company's sales; is that true? Or how would you define it?
MR. DAVISON: Objection to form.
THE WITNESS: So marketing is a -- is a

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discipline where you -- it's definitely strategic, where sales is tactical.
Marketing creates programs and projects, initiatives that position products, educate health-care providers on products, and, you know, create -- create an environment where health-care professionals, you know, desire to learn more about a product and pique their interest on a product.
BY MR. SAMSON:
Q. Okay. And then what does sales do?
A. Sales sells. So sales drives prescriptions.
Q. Okay.
A. New prescriptions, more prescriptions, et cetera.
Q. And the two, marketing and sales, work together to hopefully increase the sales of a company's whole line or specific products within the company's line?
A. Hopefully they work together.
Q. Okay. Operations. What was operations, when you said that was something you thought you might bring to the Mallinckrodt table?
A. It's kind of a catchall term. It could be a variety of things in various departments.

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I mean, I -- I've always been kind of a problem solver. I'm a person that can analyze a situation and create a plan for improvement if there are problems, or just improvement if there aren't problems.

And when I started there, I started in the imaging agents' business, which was, you know, faltering significantly. And I helped them for awhile before getting into the Medical Affairs.

Q. So is operations divorced from marketing and sales and, say, product development on the other side of things, or not?

A. It could involve all those things or some of those things, yeah.

Q. Okay. And what about operations in terms of how do we -- how do we produce "X" million generic oxycodone tablets; is that operations or manufacturing?

A. That would be manufacturing.

MR. DAVISON: Objection to form.

THE WITNESS: Which, you know, I -- I'm not a manufacturing guy. So I would have no idea how to do that better. Yeah.

BY MR. SAMSON:

Q. Okay. So -- and then improvements in

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efficiencies, that's a goal that could apply to either our operations or marketing?

A. It could.

Q. Okay. Did you have some separate, from operations or marketing, idea about improvement in efficiencies when you gave that as a third strength?

A. I had absolutely no idea what they needed in terms of operational efficiencies, but that would have happened if I would have been engaged in that particular area, which I wasn't.

Q. Okay. And then Exhibit 2 --

MS. GAFFNEY: That would be 3.

MR. SAMSON: Oh, that's right. That would be 3.

THE WITNESS: I've got a 2 here.

MR. SAMSON: You're right. We had a -- William screwed up our numbering system.

MR. DAVISON: I'm just trying to make your life difficult here.

MR. SAMSON: But the résumé did help. This is 3.

(Exhibit No. 3 was marked.)

BY MR. SAMSON:

Q. Okay. This is -- what you have now

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is Exhibit 3. And this is a consultancy agreement.

So you were hired as a consultant?

A. I was initially, yes.

Q. And it says, if you turn to the very last page, Exhibit 8, "Scope of Work." You will perform leadership abilities, and in the area of North American sales and marketing for the imaging solutions business, and also provide expertise and guidance to the imaging logistics function as required.

A. Correct.

Q. And the imaging side -- was the imaging in Covidien, too, or was it not part of Covidien?

A. It was part of it, yeah.

Q. Okay. And this is CT and radiographic imaging --

A. Contrasting.

Q. Contrasting, dyes?

A. Dyes, contrast agents, et cetera.

Q. And you said it was -- I forget the term -- not in healthy shape?

A. Not in healthy shape. It was going down.

Q. Why was that?

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A. It's a long-term problem that they had, where they did not really invest enough in the business over a period of years to enhance their product line enough to -- to continue as a growing business. So they were being surpassed by competitors who were investing in their imaging products.

Q. And you took up that work on May 1, 2009?

A. Uh-huh.

Q. Is that a "Yes"?

A. Yes. That's a yes. I'm sorry.

Q. And did you -- where was imaging headquartered? St. Louis?

A. St. Louis.

Q. Did you move to St. Louis?

A. I did. Not right away, but I did. When I transitioned from a consultant, which was this, to a full-time employee, I was required to move to St. Louis, which I did.

Q. Okay. And then -- so you worked -- and I'm going to show you -- I think that was October 26, was your -- of 2009, was your -- somewhere around there was your actual hire date --

A. Okay.

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Q. -- as a nonconsultant.
So from May 1 through end of October of 2009, you worked on the imaging side?
A. I did.
Q. And did you have any contact with the pain space at Covidien during that time?
MR. DAVISON: Objection.
THE WITNESS: I did not.
BY MR. SAMSON:
Q. And how did things go?
MR. DAVISON: Objection.
BY MR. SAMSON:
Q. In terms of --
MR. DAVISON: Sorry.
BY MR. SAMSON:
Q. -- your impact on the imaging business?
MR. DAVISON: Objection to form.
THE WITNESS: I think it was -- I would characterize it as a bit shocking to them, what I laid out and proposed. And it wasn't a quick fix type of approach, which is what they wanted. But the patient was too far gone at that point. And what I recommended, they were not willing to do. And they eventually divested the business.

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BY MR. SAMSON:
Q. What were your recommendations in global, you know, 30,000-foot?
A. There were some -- I characterize it as bottom-up types of recommendations to kind of improve the day-to-day, and some top-down recommendations to kind of improve it as a strategic level.
They were very interested in the bottom up, but they were not interested in the top down. And they didn't really -- they weren't comfortable making investments in that business at that time. And they eventually divested the business.
Q. And was imaging a place in which there was competition to come up with new products, or was it more, how do we keep our product with its current market share and hopefully grow it?
A. It was both.
Q. Okay. And were there any new products in the pipeline in imaging, when you started?
A. Not that I recall. If there were, they were minor.
Q. And none when you left?
A. Not that I recall. If there were, they were very minor.
MR. SAMSON: Okay. And then let's do No. 4, and then I think we will probably be about ready for a break.
MR. DAVISON: That would be perfect. I was about to suggest that after this exhibit.
(Exhibit No. 4 was marked.)
BY MR. SAMSON:
Q. And go ahead and review this, Mr. Morelli. I will apologize. I didn't find a traditional actual offer letter or agreement in your personnel file. But I did find this letter from -- or email strand from Lisa Britt and Herb Neuman about hiring you.
First of all, let me ask you, in what we've been through today, have I managed to get out any meaningful experience you had in the pain space up to being hired at Covidien as an employee?
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. Did I miss anything?
A. I will say you hit the high spots, yeah.
Q. Okay.
A. Yeah.

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Q. And that was pretty much Percodan and Percocet at DuPont, and a nonopioid intrathecal at -- I forget which one of the companies.
A. Elan.
Q. Elan.
A. No, there was one other one. Because it's not a controlled substance, it probably didn't catch your eye. But it's a product named Nubain nalbuphine hydrochloride. That was a Dupont product.
THE REPORTER: What was the name again?
A. Nubain, N-u-b-a-i-n, nalbuphine hydrochloride. That was an injectable analgesic, for moderately severe to severe pain, used mainly in the hospital, postoperative or intraoperative use. But it was a noncontrolled substance, but it was quite potent.
And I was involved with sales and marketing of that, basically, around the world.
Q. And what --
A. And that was dealing with anesthesiologists and surgeons.
Q. What class of drugs does Nubain fit into it? It's not an opioid; true?
A. It would compare to -- compete with and compare to morphine, a controlled substance, but

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Nubain was a noncontrolled substance.
Q. And why was it noncontrolled if it -- are you saying its effects compared to morphine?
A. Its efficacy. Its pain-relieving ability compared to morphine, but it didn't produce the euphoria.
Q. Okay. Which reduced its risk, even if it wasn't only used in hospital, of diversion and abuse?
MR. DAVISON: Objection.
THE WITNESS: Absolutely.
BY MR. SAMSON:
Q. And -- but I mean, do -- the opioids all work with certain receptors?
A. They do.
Q. Ibuprofen and the rest of the NSAIDS work with different receptors or the same receptors?
A. Uh-huh.
Q. What was nalbuphine doing in the body to provide pain relief?
MR. DAVISON: Objection to form.
THE WITNESS: It was generally believed to be a kappa agonist as opposed to a mu agonist, which the -- you know Class 2 and 3 and morphine, and those drugs, tend to be agonists at mu receptor.

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Morphine -- I mean nalbuphine was actually an antagonist at the mu receptor, an agonist at the kappa receptor. That was the belief at that time.
BY MR. SAMSON:
Q. Was nalbuphine ever a drug in which abuse was a worry?
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. Abuse by the patient?
MR. DAVISON: Same objection.
THE WITNESS: Quite the opposite. If a person who is tolerant or addicted on a morphine-like drug would receive nalbuphine, it would precipitate withdrawal because of the antagonistic effect at the mu receptor.
BY MR. SAMSON:
Q. Okay. And, basically, pain relief, no high?
MR. DAVISON: Objection to form.
THE WITNESS: Basically.
BY MR. SAMSON:
Q. Okay. Back to your letter.
A. Right.
Q. No. 4. It appears you're being hired into Medical Affairs at Mallinckrodt?

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A. Correct.
Q. Had you ever served in a Medical Affairs Division, or whatever the correct subunit is, of any other pain space company?
A. No.
Q. And from some documents we will look at later -- or, here, let me give it to you right now. Can I have 5 -- what will now be 5, Allison.
(Exhibit No. 5 was marked.)
(Witness reviewing document.)
BY MR. SAMSON:
Q. Had a chance to get through it? As I understand it, this was actually from a presentation in 2011. But I want you to turn to the second inside page there. Oops. Too far.
A. This one?
Q. No, the one that --
A. This one.
Q. -- has the slide on, "Role on Medical Affairs."
A. Oh, I got it. Okay.
Q. When you joined Covidien's Medical Affairs Department, was it your understanding that Medical Affairs was responsible for providing accurate medical and scientific information about

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Mallinckrodt products to the marketing and sales staff based on, quote, evidence-based best practices in health care, end quote?
A. Yes.
Q. So that was there before you, as the --
A. I'm not sure of the timing of all of this. But, yes, I believe that was the belief. Knowing Herb Neuman like I do, I believe that's what he believes.
Q. And Mr. Neuman was the head of Medical Affairs the entire time you were there?
A. Chief Medical Officer, yes.
Q. And is he an MDL or a Pharm.D, or what's his medical qualification?
A. MD, MBA.
Q. And that, I take it from earlier answers, suited Art Morelli, that we were going to only act on evidence-based best practices in health care to a tee?
A. Yes.
Q. Because, as you talked about both the effects of pain and the potential poor effects of opioids, you want to know what the drug is going to do based on evidence, not guesswork, and you want to

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know what the risks are based on evidence and guesswork, and you want to know how effective it is based on evidence, not guesswork?
MR. DAVISON: Objection to form.
THE WITNESS: So, yes, but that's incomplete. It's available evidence. It's good evidence. It's reliable evidence. It's validated evidence as opposed to anecdotal evidence, belief, or practice.
And the bottom line on what is considered or what is considered usable evidence by a pharmaceutical company is what the FDA approves. If the FDA doesn't adjudicate it, you really can't -- the marketing and sales organizations really can't use evidence that hasn't been adjudicated by the agency.
THE VIDEOGRAPHER: Sorry, Counsel. I just got an email saying that people on the phone can't -- are disconnected or can't hear.
MR. SAMSON: Shall we take a break?
MR. DAVISON: Yes, let's take a break.
MR. SAMSON: We are getting close.
THE VIDEOGRAPHER: Off the record. The time is 10:40 a.m.
(Recess taken.)

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THE VIDEOGRAPHER: We are back on the record. The time is eleven o'clock a.m.
BY MR. SAMSON:
Q. Mr. Morelli, let me ask you a couple catch-up questions. First of all, you were talking about DuPont having Percocet and Percodan?
A. Yes.
Q. Branded drugs?
A. Yes.
Q. At some point were they -- those brands sold to Endo, or was Endo a division or some other relative of DuPont?
MR. DAVISON: Objection to form.
Object to form.
THE WITNESS: I believe at one point DuPont did divest some products to Endo in the very early stages of Endo, yes. But I was not involved with that at all.
BY MR. SAMSON:
Q. Okay. And then let me ask you to return to Exhibit 4 for just a second. And the second page.
A. Okay.
Q. And you see here that Ms. Britt lists the -- that wants to start you as early as Monday --

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A. Oh, wait a second.
Q. -- with the following non-negotiable offer criteria.
A. Yes.
Q. Okay. Your base pay as Vice President of Medical Affairs was going to be [redacted]?
A. Correct.
Q. And is that what it became even though --
A. That's what I started with, yes.
Q. Okay. And did it go up from there during your time at Covidien?
A. It did.
Q. Okay. When?
A. Each year.
Q. And by how much?
A. In the three, four percent range, in terms of base pay increases each year.
Q. Okay. And then what does the 25 percent max at 15 no guarantee bonus opportunity line refer to?
MR. DAVISON: Objection to form.
THE WITNESS: That's considered variable -- variable compensation, compensation that you are not

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guaranteed, but you may be able to achieve based on performance or ability to achieve the objectives that you were given in the context of the company's, you know, financial health.
BY MR. SAMSON:
Q. Okay. And does 25 percent bonus opportunity, what -- what's max at 50? 50,000 or --
A. Fifty percent.
Q. Okay. So it could go --
A. Of your base.
Q. So it go from 25 to 50 percent?
A. Right.
Q. And no part of that scale was guaranteed?
A. Correct.
Q. Okay. And did you get a bonus in 2009?
A. I got -- I believe I got a bonus every year I was on salary. You know, not as a consultant, obviously. But yes.
Q. And what was -- is there a fiscal year for Covidien?
A. It was a fiscal year.
Q. And what was the start and end date?
A. The start was -- April 1st was the

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start, and March 31st was the end.
Q. So you would have been in the program roughly half a year --
A. Yeah. I think it was time adjusted.
Q. -- in 2009?
MR. DAVISON: Let him finish his question.
THE WITNESS: Oh, I'm sorry.
BY MR. SAMSON:
Q. In 2010 did you get a bonus?
A. I did.
Q. And was it 25 percent or more?
A. My recollection is I maxed out on it every year I was there.
Q. Okay.
A. Yeah.
Q. So same answer for 2011?
A. Yeah.
Q. And were you told every year why you got it?
A. I was.
Q. Okay. And part of it, you said, was overall company performance?
A. So overall company performance would create a pool of money. And then the allocation of those funds to individuals as part of their incentive

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comp would be based on their individual performance.
Q. And I take it Mr. Neuman would have judged your performance and then given you what, if anything, he thought was yours from the bonus pool?
A. Correct.
Q. Was the pool set by a given percentage, like profit, "X" percent of?
A. I don't know.
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. Okay. Now, let's go back to Exhibit 5. And I've got it as page 3. So it will probably be on the front of -- it's a slide, "Medical Affairs: Key Players in Clinical Content."
A. Yes.
Q. And clinical content, what did that mean on this slide?
MR. DAVISON: Objection to form.
THE WITNESS: It means the content that was -- the content areas that various people were in charge of.
BY MR. SAMSON:
Q. And since this presentation is called, "Field Sales Force Clinical Education" --
A. Right.

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Q. -- this would be the sector of field sales force clinical instruction that each person or each group here was responsible for?
A. Right. Yes.
Q. And you are there. And then underneath you are the PPS Team, which I found elsewhere as being pharmacovigilance and patient safety team?
A. Not pharmacovigilance. Pharmacovigilance was Eddie Darton.
Q. Okay.
A. This was the Patient and Product Safety Team, PPS.
Q. Okay. And in terms of both teaching -- and would these be educating the sales force, this presentation?
A. It would be primarily new sales representatives.
Q. Does the evidence-based goal apply to that function as well?
A. Yes.
Q. Okay. And evidence base we discussed, is scientifically and medically supported by the evidence, real evidence, whether or not that evidence reaches the conclusion that Covidien or Art

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Morelli may want to have it reach?
A. Right.
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. And basically do you believe that statements made by Mallinckrodt about its products should be judged by that standard?
MR. DAVISON: Objection to form.
THE WITNESS: Generally, yes.
BY MR. SAMSON:
Q. Are there exceptions, where you would abandon scientific/medical evidence or consensus and just go by what would be a good thing to say about the drug?
MR. DAVISON: Objection to form.
THE WITNESS: I can't think of any right now.
BY MR. SAMSON:
Q. So what did the Patient and Product Safety Team entail in this side of clinical content?
A. So we were -- my team, that was about six, seven, or so people in that PPS Team, had the responsibility of conceptualizing, creating, submitting, and implementing the Exalgo REMS. That was job number one.

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Number two, that same function for the C.A.R.E.S. Alliance.

Number three was the publications -- publications team.

Number four was the investigator-sponsored research team.

And the fifth one was the -- a program that I created and initiated, was the Medical Affairs Internal Lecture Series. So our team did all of those things.

Q. When did you start the Medical Affairs internal lecture -- lecture series?

A. Sometime early in my career in Medical Affairs there, yeah.

Q. Okay. So maybe in the last three months of 2009, maybe in early 2010?

A. Maybe, yeah.

Q. Okay. Is -- at Mallinckrodt would there be a list of what the Medical Affairs lecture series consisted of?

A. Yes.

MR. DAVISON: Objection to form.

BY MR. SAMSON:

Q. How often were the lectures presented?

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A. Quarterly.

Q. And what were the topics, as you remember them now?

A. They were a range of topics. Drug addiction was a topic. I'm just -- the ones that I remember, musculoskeletal pain was a topic. And there were others. I can't think right now.

But these lectures were conducted on-site at the corporate headquarters. They were videoed. And those videos were made available to people who couldn't attend.

Q. And who were the invitees?

A. The company at large. Anybody.

Q. Okay. So it wasn't -- it was Medical Affairs giving the lectures, but not giving them --

A. Or sponsoring them. Sponsoring them. We didn't give them, no. Outside experts, physicians, scientists gave the lecture. We did not.

Q. Okay. And then the sponsored research component?

A. What is that?

Q. Yes.

A. So various physicians, scientists, would submit proposals of studies that they wanted us to fund. We would evaluate which ones we were going

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to fund and which ones we weren't, because we received far more than we were able to fund. And the ones that we funded, we provided financial support to the investigator to conduct those studies.

Q. And in the time period where you were on the Medical Affairs team, what percentage of those submissions for possible funding were related to the opioid pain space?

A. There were -- there were some. There were some, definitely. Yeah, I can't remember the number.

Q. Some 80 percent or some --

A. Oh, no. I would say --

Q. -- 20 percent?

A. I would say about -- about 50 percent, I would say.

Q. And of the however -- what would 50 percent, during your time there, of the opioid pain space submissions be in a number, just a --

A. Like number of studies?

MR. DAVISON: Objection.

BY MR. SAMSON:

Q. Yes. Proposed studies.

A. Yeah. How many would we receive?

Q. Yes.

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A. We might receive 20 or 30 proposed. And we would fund maybe three to five, that kind of number. That kind of range.

Q. And although I'm not going to run you through it today, I assume that somewhere at Covidien/Mallinckrodt, there will be a budget for --

A. There was a budget.

Q. -- that line item?

MR. DAVISON: You've got to let him finish the questions.

THE WITNESS: Okay. I'm sorry.

BY MR. SAMSON:

Q. So we can see which ones were funded and to what degree?

MR. DAVISON: Objection to form.

THE WITNESS: I don't know. Probably.

BY MR. SAMSON:

Q. Okay. Carolinas we will talk about and Exalgo REM we'll talk about.

A. Okay.

Q. Are those the major four functions that Art Morelli and his PPS Team were involved in during the entire time you were at Covidien as an employee?

A. I think it was five. But those were

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the ones, yeah.
Q. I got medical --
A. Exalgo REMs.
Q. Oh, okay, you are right. It is five.
A. Yeah.
Q. We talked about three of them, and then REMS and the other two. That does add up to five.
Was there anyone on your PPS Team that had an MD degree?
A. No.
Q. Anyone on your PPS Team that had hands-on experience in pain --
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. -- treatment?
A. No.
Q. Anyone who was a researcher in either opioids or pain in general?
A. No.
Q. Was there an outside source for your team, then, to get that kind of scientific, slash, medical input for your functions?
A. Yes.
Q. Who?

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A. It was a panel of experts that we worked with, along with one of my direct reports on the team who was a Ph.D. He was an epidemiologist.
Q. And who was the Ph.D.?
A. Bobby Clark.
Q. And what part of the company was he in?
A. He was in my team.
Q. Oh, he was on yours?
A. Yes.
Q. Okay. What was -- his Ph.D. was epidemiology?
A. Yes.
Q. And who else was on the panel of experts?
A. He wasn't one of the panel of experts.
Q. Okay.
A. He was an employee.
The panel of experts was a group of people that we selected for their -- for their experience, their expertise, for their -- you know, a mix of different perspectives. Some physicians, some addiction-ology, some pain educators, some pharmacists, slash, lawyers, et cetera.

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Q. Was a pain management doctor named Webster, out of Utah, on the panel of experts?
A. He was.
Q. And he ran Lifeline or Lighthouse? Lifetree?
A. Lifetree.
Q. And was he on the panel the whole time you were there?
A. Yes.
Q. And he was there as a voice of experience and integrity in the pain treatment community?
MR. DAVISON: Objection to form.
THE WITNESS: Knowledge, experience, and integrity, yes.
BY MR. SAMSON:
Q. How -- what was the number? You may have given it to me.
A. Of people on this panel?
Q. Yeah.
A. I'm saying between five and ten.
Q. Okay. Any other pain management types, like Dr. Webster, whose name you recall -- names you recall, multiple?
A. They were all involved with pain

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management of one aspect or another. Either pain, you know, treatment, pain education, pain -- you know, pain patient interaction for addiction, things like that. Yeah.
Q. Okay. Any other names that you recall?
A. There's more names, if you want more.
Q. Okay. Yeah, please give me --
A. So Deborah Gordon, who is a nurse educator, out of Washington, University of Washington. David Brushwood, Pharm.D/lawyer out of Florida at the time. Steve Passik, an addiction specialist, Ph.D.
Let's see. Maybe more names will come to me. I can't remember right now.
Q. You're doing pretty good.
A. Thank you.
Q. So you talked about the Exalgo REMS, the C.A.R.E.S Alliance, the -- deciding what submitted proposals would be sponsored research, Medical Affairs lecture series, an in-house production, and drug addiction for musculoskeletal pain. What was that one?
MR. DAVISON: Objection to form.
///

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BY MR. SAMSON:
Q. Or did I write that down wrong?
A. I don't -- no. It was treatment of musculoskeletal, that lecture.
Q. Sorry. And was that a single lecture?
A. Each of these are single lectures, yeah.
Q. Okay. So of those five areas for your team during your time at Mallinckrodt, how much of your team time was spent on the Exalgo REMS?
A. Early on, most of it. As things progressed forward, less time needed on that, more time needed on the C.A.R.E.S. Alliance.
Q. Did those two always take up the majority of your team's time?
A. They did.
Q. So dealing with the proposals for research grants, a five percent or a ten percent or --
A. I would say ten percent.
Q. Okay. And then Medical Affairs lecture series?
A. Five percent.
Q. And the treating musculoskeletal pain

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lecture?
A. No, that was -- those are just individual lectures, so that would all come under the lecture series.
Q. So five percent for the lecture series?
A. Yes.
Q. And any other appreciable repeatable blocks of time spent --
A. The investment of sponsored research, did you say that?
Q. I did. And I thought you had said ten percent?
A. Okay. Okay. So -- so do we have everything?
And then the rest of it is Exalgo REMS and the C.A.R.E.S. Alliance.
Q. So roughly in the 85 percent range for those two?
A. Something like that, yeah.
Q. So did your PPS Team embrace both Covidien-branded pain space drugs as well as generics?
MR. DAVISON: Objection to form.
THE WITNESS: Specifically on, like, a named

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product basis, we had no involvement with generics.
MR. SAMSON: Okay.
THE WITNESS: However, the C.A.R.E.S. Alliance was about all of chronic pain and all of opioids, regardless of whose products they were, ours or somebody else's.
BY MR. SAMSON:
Q. Okay. And was there -- what do you recall being Covidien's provision of information on generics to the C.A.R.E.S. Alliance?
MR. DAVISON: Objection to form.
THE WITNESS: There was no interaction between the C.A.R.E.S. Alliance effort and our generic drug production and distribution.
BY MR. SAMSON:
Q. Okay. So C.A.R.E.S. Alliance took care of -- of whatever it was going to do with the generics without input from Medical Affairs at Covidien?
MR. DAVISON: Objection to form.
THE WITNESS: You have to rephrase that question. I don't understand it.
BY MR. SAMSON:
Q. I'm trying to follow up, because you said C.A.R.E.S. Alliance dealt with generics and

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branded drugs.
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. True?
A. True. So let me -- but not just Covidien's products. Covidien's products were irrelevant to the C.A.R.E.S. Alliance. It was -- we were agnostic as to whose products, the particular molecules were from. We were interested in safe and appropriate use and management of chronic pain no matter whose products were being used. It was best practices. It was like a best practices approach.
Q. Okay. And what I'm trying to figure out is Covidien, you are aware the whole time you were an employee, sold generic opioids?
A. Oh, yeah, I was aware of it.
Q. Okay. And those were, certainly from 2009 to 2011, was not a trough in the nationwide sale of opioids of all sorts; true?
MR. DAVISON: Objection to form.
THE WITNESS: I have absolutely no idea what the sales of any of these products are or were.
BY MR. SAMSON:
Q. That wasn't filtered back up to you guys to give you a focus on what we might need to do

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in our scientifically-based, medical best evidence role to decrease oversale, if there was such oversale?
MR. DAVISON: Objection to form.
THE WITNESS: Absolutely not. It would be the last people I would ask, people in the industry anywhere, of a sales or marketing organization what they think we need to do for patient safety. Okay.
BY MR. SAMSON:
Q. You speak as a veteran that knows -- has formed an impression that salesmen will sell --
MR. DAVISON: Objection.
BY MR. SAMSON:
Q. -- and are not interested in hearing -- in hearing downsides of their product?
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. Is that true?
A. So it's maybe true in some cases. But you're not going to -- they're not a reliable source of information on the global patient management of pain. I wouldn't go to a sales rep to ask a sales rep or a marketing director, how do you think is best practices in patient diagnosis and patient management? I would go to a physician or an

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expert in that field.
So what Mallinckrodt was selling up, down, or sideways was of really no interest to me whatsoever.
BY MR. SAMSON:
Q. I'm talking about, though, you're developing tools; correct?
A. Correct.
Q. To avoid oversales of opiates, avoid diversion and overdose deaths, and those sorts of things, as best you can by developing tools for the proper prescription of opioids; correct?
MR. DAVISON: Objection to form.
THE WITNESS: Correct. But incomplete. It wasn't just about things to avoid. And there are plenty of things to avoid. It was also about things they should be done -- that should be done to better manage patients and to reduce harm to patients.
BY MR. SAMSON:
Q. Okay. My question is, within management, operations, and control, was there any passing of that information from Medical Affairs, as you developed it, to the generic sales force?
MR. DAVISON: Objection to form.
THE WITNESS: Absolutely not. I don't even

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think we had a generic sales force. I don't even know what they had in generics.
BY MR. SAMSON:
Q. So at no point were you aware whether Mallinckrodt's generic -- sales of generic opioids, during the time you worked there, were miniscule compared to their branded drugs?
MR. DAVISON: Objection to form.
THE WITNESS: I have no idea what their generic sales were. I don't really know what the branded sales were. It's not my job to know that. I don't need to know that. I don't want to know that.
BY MR. SAMSON:
Q. Safe to say, then, that nobody on your team doing its job, including C.A.R.E.S. Alliance and trying to get the correct use of opioids for pain control, ever did anything with Mallinckrodt's either branded sales teams or generic sales operatives?
A. Oh, we did --
MR. DAVISON: Objection to form.
THE WITNESS: We did plenty with the brand sales team.
MR. SAMSON: Okay.
THE WITNESS: We did a lot with them.

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MR. SAMSON: Yeah. And I thought --
THE WITNESS: Yeah.
MR. SAMSON: -- I saw documents to that effect.
Q. But nothing in terms of Medical Affairs, Art Morelli controlling the problem of opioids to the generic Mallinckrodt business, that you were aware of?
MR. DAVISON: Objection to form.
THE WITNESS: Correct.
BY MR. SAMSON:
Q. Did anyone tell you that generics -- don't go to the generics, from higher management?
A. No one had to tell me.
MR. DAVISON: Objection.
BY MR. SAMSON:
Q. Because of why?
A. Because I know it's not appropriate. It's not a fit. It doesn't -- they don't -- they are not -- they are not structured to do anything with it. And I don't care what -- they may have an opinion, or whatever. Frankly, I don't care what it is. I care what Herb Neuman and the FDA think and my expert panel think.
Q. And that's you and Mallinckrodt

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gathering what you believe to be a very balanced, correct approach to this class of drugs, opioids, in the treatment of pain and balancing all the factors; true?
MR. DAVISON: Objection.
THE WITNESS: Not really true. So let me kind of clarify for you.
MR. SAMSON: Okay.
THE WITNESS: So in the eyes of the FDA, a balanced approach generally refers to risks and benefits of a drug, any drug. That's what the FDA requires, a balanced approach to physicians, benefit and risk.
The C.A.R.E.S. Alliance and the Exalgo REMS was nothing about benefit. It was all about risk mitigation and optimizing therapy, of whatever drug you might be using, by preventing harm to patients. It was not balanced. It was imbalanced in favor of safety.
BY MR. SAMSON:
Q. And that message, as far as you know, was not in any way provided to the generic side of Mallinckrodt opioid sales while you were there?
A. Correct.
MR. DAVISON: Objection.

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BY MR. SAMSON:
Q. Medical Affairs had a budget; true? I'm assuming.
A. It did.
Q. And you told me that one part of that budget that was under your team's responsibility were the grant proposal decisions?
A. Yes.
Q. How about key opinion leaders, speakers bureaus, or other things like that, were those under your team or --
A. No.
Q. -- some other part --
A. Speakers bureaus, I had nothing to do with speakers bureau. That's a commercial function, with their own budget and their own process.
Q. Okay.
A. KOLs, only -- only the KOLs that were on our advisory -- you know, safety advisory board were the KOLs that I would be dealing with.
Q. And they were -- KOLs, in the general sense, were not on Medical Affairs budget?
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. Is that true or not?

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A. No. They would receive compensation for serving on the C.A.R.E.S. Alliance panel of experts that met quarterly.
Q. Okay. But did KOLs receive, to your knowledge, from Mallinckrodt other payment for other work that they might do?
A. I'm sure they did. I don't know.
Q. But not out of Medical Affairs budget?
A. Not out of Medical Affairs, yeah.
Q. And that was -- is commercial a known subentity? You said it was off of commercials.
A. They have a budget. They have a budget line for, for example, speakers bureau. So they give "X" number of lectures, you know, over the course of the year at various places, and they pay for that. I don't pay for that.
Q. Okay. Did you, or anyone else that you know of at Medical Affairs, have anything to do with picking the speakers?
MR. DAVISON: Objection to form.
THE WITNESS: I had nothing to do with it. I don't know who else had stuff to do with it.
BY MR. SAMSON:
Q. Okay. In your term of 2009 to 2011,

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what was the budget for the grant proposals?
A. The grant proposals. I'm sorry. I don't recall the number.
Q. But that --
A. But as a percent, you know, compared to the whole budget, it was quite small.
Q. What -- what were the big chunks of the Medical Affairs budget in your time?
MR. DAVISON: Objection to form.
THE WITNESS: Well, people's salaries, and so forth. But apart from that --
BY MR. SAMSON:
Q. Can I call that overhead?
A. Yes, overhead. Apart from that, it was -- the C.A.R.E.S. Alliance was a huge part of it.
Q. And do you recall yearly budget figures from Medical Affairs budget to C.A.R.E.S. Alliance, which was launched at Pain Week 2010, as I recall?
A. I think so.
Q. And so it would have had some developmental expense --
A. Right.
Q. -- prior?
What was the annual budget from Mallinckrodt

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to C.A.R.E.S. Alliance?
A. I can't give you an exact number, but it was in -- it was multiple millions of dollars a year. Not 20 -- not 20 million and not 1 million, you know.
Q. Somewhere between 20 and 2?
A. Right. Yeah.
Q. And was that simply -- Covidien owned C.A.R.E.S. Alliance; true?
A. Correct.
Q. And Covidien owned the trademarking of it; correct?
A. Correct.
Q. So was the 2 to 20 million, wherever we find a budget document and come up with it, what did that go to, as you understood it, within C.A.R.E.S. Alliance?
A. So it went to the creation and production of the various tools that we provided to health-care professionals. And each tool had, you know, a developmental expense, a production expense, et cetera. Not a distribution expense because that was pretty small. But it had a development expense, was the biggest part of it, and production expense.
It went to -- quite a bit went to

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educational programs, like webinars that we conducted, to educate physicians in online webinars about safe opioid practices. It went to a whole program I developed called "Expert On Call," which created the ability of physicians to call one-on-one an expert in the field if they thought they needed some, you know, additional insight into certain problems they might be having with their patients. And that was something we funded. And it went pretty well.
Of course, that -- those conversations were to be between the physician in their office and the expert, wherever they would be, without any participation by the commercial people. So it's a peer doctor to doctor kind of thing.
Another one was "Meet the Expert Series." So at various conventions -- you've probably been to pharmaceutical exhibits at various medical societies. You've been to that; right? And you go into the exhibit --
Q. Only in the veterinary market.
A. Okay. So you go into the exhibit room, and there's booths all over the place, right, with advertising and sales reps running around. What I did is I carved out a separate, cordoned-off area

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of a Medical Affairs portion of the booth where the commercial people didn't -- couldn't go, and that was staffed by our physicians, our pharmacists, and so that they could ask -- the participants at the meeting who were physicians could ask, you know, questions about the drugs from a peer, a peer kind of thing.
But what I added to that, that hadn't happened before, it's called a "Meet the Expert." So I would carve out a schedule, hour-by-hour schedule of various experts from the -- you know, from the pain community to sit there, and a doctor could walk right up and have a one-on-one conversation unimpeded by -- by anybody else, if they had any questions that they wanted to ask, a Lynn Webster or a Steve Passik or other people too.
So those are the kind of -- that's a flavor for the kinds of programs. And I can tell you, they are very expensive. But it's worthwhile.
Q. And where did the ordinary speakers budget come out of?
A. Commercial.
Q. And non-C.A.R.E.S. Alliance KOLs, or the few KOLs that were under Medical Affairs, the rest of those, where did that budget come out of?

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MR. DAVISON: Objection to form.
THE WITNESS: I don't recall there being a separate KOL budget, but there were separate non-C.A.R.E.S. Alliance, you know, activities that some KOLs might participate in that they got compensated for. But I wasn't involved with that. Yeah.
BY MR. SAMSON:
Q. Okay. About the Rx FMEA analyses?
A. Right. So that was quite an -- quite an expensive endeavor. So the Rx FMEA analysis, that was done during the formation and creation of the Exalgo REMS.
Are you familiar with Rx FMEA? Maybe you're familiar with FMEA, Failure Mode and Effects Analysis. Right.
So a Failure Mode and Effects Analysis is a recognized process used to determine why things go wrong in any system. It's often used in the nuclear regulatory space. So it maps out a process. It finds weak points in the process. It maps out the severity and frequency of failure modes in the process, and then it maps out specific solutions against those failure modes to reduce the probability of those failure modes taking place.

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So we did that exercise for the Exalgo REMS to make sure we had more of a science-based approach rather than a shooting-from-the-hip approach to the things we wanted in our REMS.

Q. Rather than thinking you knew what was going to happen, you went through a very detailed process --

A. Right.

Q. -- to identify failure modes and sub-modes that contributed to them; correct?

A. Exactly.

Q. And then looked at those failures and said, what can we possibly do to stop the failure from happening, after you had already ranked from least to worst the consequences of failure in that particular mode?

A. Yes.

MR. DAVISON: Objection.

BY MR. SAMSON:

Q. All right. Were the Rx -- was the Rx FMEA system and analysis ever applied to Mallinckrodt's generics?

A. Not to my knowledge.

You can't apply it to a product. You have to apply it to a system, a use system or an

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operational system.

Q. Well, and --

A. Like management of chronic pain, would be a system you could apply it to.

Q. Well, you certainly applied it to Exalgo within --

A. I did.

Q. -- Medical Affairs; true?

A. I did. Well, the use of Exalgo in the treatment of chronic pain. Yeah.

Q. But the use of generic oxycodone, generic hydromorphone, any other generics that Mallinckrodt was selling from your time, 2009 to 2011, into the opioid pain space, no effort at Rx FMEA analysis was made; true?

MR. DAVISON: Objection to form.

THE WITNESS: Not to my knowledge.

BY MR. SAMSON:

Q. If you were king, would you like to have seen the same system applied to generics?

MR. DAVISON: Objection to form.

THE WITNESS: It potentially could have some utility. We made the FDA aware of what we were doing, and they were very supportive of a science-based approach because they are a

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science-driven FDA organization. But the fact of the matter is, the learnings from the Exalgo FMEA process created insights and tools that are actually fairly widely applicable across the opioid space.

So, you know, there's -- you could, you know borrowed -- you know, borrowed ideas here are always good.

BY MR. SAMSON:

Q. But we're talking about a single company --

A. Right.

Q. -- that applies them, because it believes in them, to Exalgo; correct?

MR. DAVISON: Objection to form.

BY MR. SAMSON:

Q. The Rx?

A. Uh-huh.

Q. FMEA?

A. Uh-huh.

Q. At the same time, that same company is selling generic opiates -- opioids and elects not to apply the analysis to those; true?

MR. DAVISON: Objection to form.

THE WITNESS: What the decision-making process was, the fact of the matter is, as far as I

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know, they didn't. But what their decision-making process was, I have no idea. I was not involved with it.

BY MR. SAMSON:

Q. Okay. Were -- did you have to get FDA permission to develop and apply the Rx FMEA analysis to Exalgo?

A. No.

Q. And do you know of any reason why one would have to get FDA permission to do that for generics?

A. No.

MR. DAVISON: Objection to form.

BY MR. SAMSON:

Q. Let's go back to 2009, whether in imaging -- joining in imaging --

A. Where was I in 2009?

Q. I know you were going to try and turn around the imaging department for part of the era.

Were you aware there were a lot more opioids being sold in America and people were becoming concerned about it?

MR. DAVISON: Objection to form.

THE WITNESS: More than what?

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BY MR. SAMSON:
Q. More than had been sold before?
MR. DAVISON: Objection to form.
THE WITNESS: Generally speaking, I would say I had that impression. I couldn't document it, but I know -- what was more important to me was the FDA was concerned about the safety. The safety of drugs in general. And that's why REMS was a program that they adopted. And the first REMS were not opioid REMS. They were nonopioid products that had serious risks.
BY MR. SAMSON:
Q. Which ones?
A. I will think of the name of the product in a second. But it was an acne product that had a teratogenic risk. And there are many classes of drugs that have risks that are the FDA hot button risks, beyond abuse and death and overdose, which is an FDA hot button risk.
But teratogenicity is a hot button risk, and liver function tests are a hot button. And there's many others. But there are about seven or eight that are their hot buttons.
Q. In general terms, when you took the job at Mallinckrodt in 2009, had you heard the term

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"opioid epidemic"?
MR. DAVISON: Objection to form.
THE WITNESS: I can't remember what I heard. But I would say, yes.
BY MR. SAMSON:
Q. And since you had been involved with the opioids back in your DuPont days, that was something that was different. Was there an opioid epidemic back in the days of DuPont's opioid drugs when you were there?
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. Identified as such in public documents?
A. Certainly not at a marquee, you know, media level, no. Not that I can recall.
Q. And Percocet and Percodan were abusible; correct?
A. Very abusible.
Q. Okay. And what was the dose of Percocet/Percodan?
A. One to two tabs, Q 4-6h.
Q. And what was the amount of active ingredient in those one to two tabs?
A. Approximately 5 milligrams.

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Q. Okay. When you came back into the opioid space at Mallinckrodt, was it a surprise to see people taking 30 milligrams of Oxycontin three, four times a day?
MR. DAVISON: Objection to form.
THE WITNESS: It wasn't a surprise as much as it meant to me, why? Why were they on that level of dose?
BY MR. SAMSON:
Q. But it was certainly higher doses than you had been used to in your earlier opioid experience?
A. Probably, yeah.
Q. It seems to me, fair to say, that your personal actions, while at Mallinckrodt, were to better understand, and then hopefully influence for better patient outcomes, this increased use of opioids in the chronic and acute pain space?
MR. DAVISON: Objection to form.
THE WITNESS: More the chronic space. But really, the C.A.R.E.S. Alliance was opioids in general in chronic pain. And then the Exalgo REMS was the safe use of Exalgo, you know, just Exalgo, which is chronic pain.
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BY MR. SAMSON:
Q. Okay. And to make evidence-based decisions addressing opioids, during the time you were at Mallinckrodt, do you agree that one thing that's a real important factor is a pain-and-science-based data on a given opioid's effectiveness at relieving either the chronic pain or the acute pain?
MR. DAVISON: Objection to form.
THE WITNESS: That's one thing. It's not the only thing that's important. But that's one thing that's important.
BY MR. SAMSON:
Q. Because to the extent that the medication doesn't really effectively relieve the pain that it's being given for, it doesn't have much -- as much benefit as one that does; true?
MR. DAVISON: Objection to form.
THE WITNESS: That's true. But you have to understand that the only organization that's -- whose opinion and whose belief really matters on that particular question is the FDA. To a pharmaceutical company, that's the only thing that matters. And we -- we have to go on their judgment, not on our judgment.

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BY MR. SAMSON:
Q. So, in your view, if the FDA says that this is an acceptable drug for medium to severe chronic pain, and you become aware of that it doesn't work for headache pain, or some other sort of pain, there's no bucking the FDA in terms of your analysis of the risk/benefit of that drug for a pain that may not be affected by it?
MR. DAVISON: Objection to form.
THE WITNESS: So in the case of headache, headache is a separate part of pain. Drugs that are indicated, generally speaking, for moderate to moderately severe pain, or even severe pain, are not indicated for the pain of headache. Headache has a different mechanism. So drugs have to be specifically indicated to treat headache.
So I wouldn't be able to tell you -- so if you have -- if you have a drug that's indicated for a moderately severe pain, you cannot promote it for headache. You don't have that indication.
So if you are receiving reports, which is the other part of your question, about people using a drug and getting certain results, that's basically a side effect that has to be reported to the agency in your Periodic Update Report. And the FDA looks at

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all of that.
BY MR. SAMSON:
Q. Okay. What about chronic low back pain, was that part of the FDA's indications on the label for Exalgo?
A. Chronic low back pain would be legal, would be a legal part of the indication, yeah -- legitimate, I meant to say. Legitimate part, yeah.
Q. So if Mallinckrodt was reading, as your department would, scientific publications in the pain world and saw that chronic low back pain was not showing very healthy evidence of being effective by the opioids, you think that there's no -- nothing that Mallinckrodt needs to do until the FDA makes it change the label to say, except not for low back pain, chronic low back pain?
MR. DAVISON: Objection to form.
THE WITNESS: So, Mark, anybody can do a study on anything they want and hopefully get it published. We can't be dancing around for every publication that comes out.
So we did the studies to approve Exalgo that the FDA required us to do. We met the standard of performance in terms of statistical significance to get the product approved. And I don't really recall

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all the pain conditions that were in that studied population. I believe there were some low back pain and osteoarthritis of the knee and other types of somatic pain, chronic pain. But if you have the indication, you promote based on indication.
If there's publications cropping up to support or deny what you're doing, you can't change what you're doing based on some random publication unless your label changes.
So you have to remember also that Exalgo was approved as a second-line drug, not a first-line drug. So it behooved Covidien, Mallinckrodt, to ensure that it was being used appropriately. I just want to show you how deep we dove on this thing.
So how are you going to know when you see your prescription data if it's being used as a second line? How are you going to know that? You don't know that. You don't know that unless you make an effort to find out.
So I commissioned a retrospective chart review of physician charts in a defined geographic area with high Exalgo use, done by a CRO, to see if the message was getting across to physicians, and they were documenting in the chart, that, in fact, they were using it to patients who were already

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tolerant -- excuse me, already tolerant to an opioid.
BY MR. SAMSON:
Q. And how --
A. And we did that study.
Q. And "tolerance" simply means they have been prescribed an opiate -- opioid at some point prior in their life and didn't have a bad reaction to it?
MR. DAVISON: Objection to form.
THE WITNESS: I don't know about the bad reaction. But they had to have been on an opioid of a certain potency for a certain amount of time. Because tolerance to the opioid is tolerance to the side effects. The FDA is worried with safety here, right.
MR. SAMSON: Right.
THE WITNESS: So they wanted to make sure that the patients being exposed to this drug had some level of tolerance, because it's a potent drug. So that tolerance is like an insurance policy, that you're not going to get a hyper reaction by the patient. So we did the data dive. It was very expensive. We can't do it across the whole country.
BY MR. SAMSON:
Q. And the --

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A. And it showed that --
Q. I'm sorry.
A. -- it was moderately -- you know, not a hundred percent, obviously, but mostly it was being used in the right way.
Q. Where was that study done?
A. I don't recall. I don't recall. But it was somewhere in the east part of the United States. That's what I remember.
Q. And did that study have a name that we can search through the multitude of documents?
A. Oh, I don't recall. I don't recall.
Q. In terms of the FDA approval test, do you recall that one of the two studies was bunionectomy?
MR. DAVISON: Objection to form.
THE WITNESS: I don't recall that, no.
BY MR. SAMSON:
Q. How much do you think bunionectomy predicts about effective pain relief in another condition other than bone surgery?
MR. DAVISON: Objection to form.
THE WITNESS: I can't comment on that. I'm not a health-care professional. But I can tell you it's a standard study requested by the FDA in

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multiple drugs over multiple years.
So bunionectomy is one of their go-to studies. But I don't know how comparable it is or how incomparable it is. All I know is we got an approved indication from the FDA. I'm not going to go to school on what the FDA is telling me. I'm going to believe them. I have got a lot of work to do before I challenge the FDA.
BY MR. SAMSON:
Q. And opioid tolerant is the -- is the other side of that opioid naive?
A. It is.
Q. And did your deep dive study look at whether or not in the use that was under the study, the tolerance that you found or the physician wrote, was a true second line? Like they have had opioid A for this pain that they are here to see me about today, or it isn't -- they had some opioid remotely in the past and had no problem with it?
MR. DAVISON: Objection.
BY MR. SAMSON:
Q. Either of those would show up as opioid tolerant; correct?
MR. DAVISON: Objection to form.
THE WITNESS: No.

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BY MR. SAMSON:
Q. No?
A. The second one is not opioid tolerant. If you're on opioids and then you're off them for a fair amount of time, they wash out of your system, and you lose the tolerance, and then you have to re-establish tolerance. That would be the proper way of looking at it.
Q. Okay.
A. If you're opioid tolerant last year, it's not helping you this year.
Q. And did your study ensure that opioid tolerance was following that more restrictive definition?
MR. DAVISON: Objection to form.
THE WITNESS: It was largely reassuring. The results were largely reassuring that the message was getting across.
BY MR. SAMSON:
Q. So back to, if you get reports from the outside medical literature that opioid A or B or C does not appear to be very effective against a certain type of pain, is it your testimony that Medical Affairs at Mallinckrodt would not do anything in response to that?

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MR. DAVISON: Objection to form.
THE WITNESS: So I am not the person in Medical Affairs at Mallinckrodt who would be making such a decision. It would be our Pharm.Ds and our physicians, like on that chart, Eddie Darton and Herb Neuman. Those would be the people who are doing it. Not me. And I will just follow what they tell me.
BY MR. SAMSON:
Q. And do you believe, based on your devotion to ensuring the best possible use of opioids in the pain space, that they would take notice of that and deal with it in some way?
A. I believe they would.
MR. DAVISON: Objection to form.
THE WITNESS: I believe they would, based --
BY MR. SAMSON:
Q. Because that --
A. -- on my interaction with them and my confidence in their high standards of performance and ethical behavior, that they absolutely would.
Q. And because you personally believe the more question there is about its effectiveness, the less risk there has to be to make it a reasonable decision to give that drug for that specific pain type; true?

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MR. DAVISON: Objection to form.
THE WITNESS: I don't understand the question. Say that again.
MR. SAMSON: Sure.
Q. All of pain medication, and especially opioid provision, is based on a balancing of the risk -- expected risk and the expected benefit?
A. All drugs, but yes.
Q. Correct. And the opioid effect that you're looking for in prescribing it is that it reduces the patient's pain; true?
MR. DAVISON: Objection to form.
THE WITNESS: That's one of the things you're looking for, yeah. That's the primary thing you're looking for.
BY MR. SAMSON:
Q. What else?
A. You're hoping -- you're hoping that the patient, you know, also can return to ambulation, can return to work, et cetera, et cetera. Yeah.
Q. Those are simply secondary effects?
A. Those are secondary.
Q. Of the absence of pain?
A. Correct.

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Q. Or decrease in pain?
A. Correct.
Q. So that's the benefit?
A. Right.
Q. Of an opioid, a contemplated opioid prescription; correct?
A. Correct. Correct.
Q. And the risks -- you know a long line of them -- there's internal, you know, bad reactions, not opioid tolerant, there's potential diversion, there's overdose, there's depression of respiration, there's a long and healthy list of risks to any opioid prescription?
MR. DAVISON: Objection to form.
THE WITNESS: Yes.
BY MR. SAMSON:
Q. So if the effectiveness is criticized and may be less, that's going to make it harder to be reasonable in prescribing the opioid because the risks aren't going to change? They are what they are for a given patient; true?
MR. DAVISON: Objection to form.
THE WITNESS: So I understand what you're saying, Mark, but that's not how I approach things. Okay.

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Here's how I approach things in my responsibility when I was at Mallinckrodt. I have nothing to do with the efficacy of the drug. I can't change the efficacy. There's no program I can give a physician, there's no tool I can give a physician to make X, Y, Z drug more effective.
But what I can do, I can give physicians tools and programs that can mitigate risk and prevent harm. That's what my focus was on. I wasn't involved in any balance. I didn't care about the balance. That's for them to judge. I cared about preventing harm.
BY MR. SAMSON:
Q. And to not question, but probably affirm your belief in the way you went about your job, you have to agree with me on a general level, even though it wasn't your job, if the opioid is less effective at reducing pain, the risk has got to go down to make the balance in balance; correct?
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. In a -- in a sane world of prescription?
MR. DAVISON: Same objection.
THE WITNESS: In a theoretical construct

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that you've outlined, of course. It would be true for any drug.
BY MR. SAMSON:
Q. I agree with you. And -- okay.
Back to some generics questions, and you may not know any answers.
Did you know, when you joined Covidien, that Mallinckrodt sold both active pharmaceutical agreements, the bulk materials to other manufacturers?
A. I did -- I was aware of that, yeah.
Q. Did you ever have any duties in Medical Affairs about that part of the business?
A. The API business?
Q. Yes.
A. No, I did not.
Q. And Mallinckrodt also used some of the API that it made to manufacture generics?
A. Right.
Q. And sold those; correct?
A. I believe so, yes.
Q. Okay. And do you know whether they sold them to other manufacturers or simply directly to -- through distributors to users?
MR. DAVISON: Objection to form.

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THE WITNESS: They sold them to other manufacturers.
BY MR. SAMSON:
Q. Do you know whether they sold any through distribution centers --
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. -- for patient use?
MR. DAVISON: Sorry. Objection to form.
THE WITNESS: So you started talking about API, and then you moved over to dosage form. So you want to know about the API?
BY MR. SAMSON:
Q. No. Dosage.
A. Oh, dosage.
Q. The API, that's just obviously -- that's just going out in bulk powder and is going to get made into whatever somebody else makes it into?
A. Yes. And that was a business they had. So the Tylenol that you buy in the store, that API is Mallinckrodt's -- or acetaminophen.
Q. They were, in fact, the world's largest manufacturer of it; correct?
A. As far as other API, I don't know. As far as dosage form of finish product or

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semi-finish product, I don't know.
Q. Okay. So you don't even know if Mallinckrodt distributed, sold to distributors for ongoing sale to patients, generics, opioids?
A. No.
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. When you joined Mallinckrodt, had you ever heard the term Oxy Express?
A. No.
Q. When did you first hear that term?
A. Right now. Today.
Q. Okay. You have no idea what that means?
A. I have an idea what it means, but I don't know if it's accurate or not.
Q. Okay. Tell me what you think it means.
MR. DAVISON: Objection to form.
THE WITNESS: What I have a picture in my mind of is, you know, a string, a linkage of people diverting and abusing drugs. That's the painting -- the picture it paints to me.
BY MR. SAMSON:
Q. All right. And you never heard of it

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applied to Florida pill mills and other sources, and being driven up I-75 to the upper Midwest as well as to Appalachia?
MR. DAVISON: Objection.
THE WITNESS: I am aware of pill mills, the existence of pill mills, but I wasn't aware of the term Oxy Express.
BY MR. SAMSON:
Q. Did anyone at Mallinckrodt, while you were there, discuss especially Florida pill mills or pill mills in general with you?
A. Absolutely.
Q. Who?
A. Oh, let me think. Well, we -- in our training of sales reps, we train them as part of the Medical Affairs portion of the training, we educated them on what to look for in terms of pill mills; to report those, and to stay away from those.
Q. Okay. And what were the indicia of pill mills?
A. Generally speaking, lines out the doors, license plates from various states in the parking lot, doctor's office next to a pharmacy, patients going through one after another, bing, bing, bing, bing, in short periods of time. High patient

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flow, those types of things.
Q. Okay. Did you at Medical Affairs follow up to see whether or not that instruction was put to use?
MR. DAVISON: Objection to form.
THE WITNESS: We received reports, yeah. We received such -- those reports.
BY MR. SAMSON:
Q. And did you receive both reports of salespeople calling on pill mills and having to be reinstructed, so to speak, that a place they were going was a pill mill?
A. No.
MR. DAVISON: Objection.
THE WITNESS: We received reports of they walked up -- or walked in and walked out.
BY MR. SAMSON:
Q. Ms. Cathy Jackson, who you remember, maybe?
A. I don't, actually, but --
Q. Okay.
A. Yeah.
Q. -- told us --
A. Our paths may have crossed. I don't know.

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Q. -- told us last week that she thought the ability of Florida physicians to both prescribe and dispense opioids was one reason why Florida was a hotbed for diversion.

Did you even know about that?

MR. DAVISON: Objection to form.

THE WITNESS: I know that the prescribing and dispensing linkage, there was a big problem, yeah. But I don't know about the legal -- legality of it.

BY MR. SAMSON:

Q. And I think you testified earlier that you really didn't even know how Exalgo sales were going; is that --

A. That's true.

Q. -- correct?

Okay. And didn't have any sense of how many Mallinckrodt generic oxy opioids were being sold in Florida or anywhere else?

A. True.

Q. True for the entire time you were there?

A. Yeah.

Q. Never any conversations with Mr. Neuman, perhaps, or anyone else in Medical

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Affairs about the opioid epidemic, whether your guys's fault or other manufacturers' fault?

MR. DAVISON: Objection to form.

THE WITNESS: So I wasn't focused on fault. I was focused on solutions and prevention, not on fault. There's plenty of fault, you know, that people like to spread around and blame. I'm focused on solutions.

I'm not focused on why the -- who was responsible for the cars crashing into one another. I want antilock brakes and seatbelts and driver training.

BY MR. SAMSON:

Q. I understand that. But you're also not living outside of this world, and in particular the United States, and you're working for a pharmaceutical company. It doesn't seem possible that you did not have discussions while you were at Mallinckrodt, slash, Covidien with other people in Medical Affairs about the opioid epidemic?

A. No, we discussed --

MR. DAVISON: Objection to form.

THE WITNESS: We discussed the opioid -- the problems that existed in society related to opioids.

MR. SAMSON: Okay.

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THE WITNESS: And that's why we created the C.A.R.E.S. Alliance, to help try to solve that problem. Because my experience with the opioid, so-called opioid crisis, is it was another report, another report, and another report as to how many people are dying. Not a report about what we are going to do about it. That's what I wanted to create. Do something about it.

BY MR. SAMSON:

Q. It's fair to say, then, that what you picked up, both inside and outside Mallinckrodt during your time on Medical Affairs, convinced you that the effects of whatever was happening in the opioid space were enough to require you to try and develop a countermeasure against it?

MR. DAVISON: Objection to form.

THE WITNESS: We have a massive problem. We have a massive problem that is taking place in this country that's killing people. Yes. But sitting here, and if it -- if the discussion, you know, in some company somewhere never goes further than that, we didn't do any good about it. Right? We just -- another rearticulation of the problem.

I was tired of rearticulating and complaining about a terrible problem without trying

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to fix it. I was going to be the start, an alliance, of companies to work together to try to effect a solution.

BY MR. SAMSON:

Q. And Mallinckrodt supported it for awhile; true?

A. They supported it while I was there, yes.

Q. And yet you were only there a couple of years?

A. I can only do what I can do when I'm there with the support of my team, Herb Neuman, and the CEO, who supported it.

Q. He did support it?

A. He did. That's why we got the budget that we got.

Q. And why did you leave?

A. Frankly, I had had enough of living in St. Louis when I was supporting a home in San Diego. And my wife, being in the Bay Area helping with our daughter's childcare and triangulate, you know, three households, I was frankly tired of it. And I hated St. Louis. So I wanted to get back to San Diego.

So I figured -- I felt that I had made a big

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impact. I had done what I could do. I got this program developed, launched, implemented. I had a well-trained team that could carry on. So I figured it was time. I'm not so young that I'm building my career, you know.

Q. Okay.

MR. DAVISON: Mark, we have been going a little over an hour. It is time for a break.

MR. SAMSON: Yes. Let's take a break.

THE VIDEOGRAPHER: We are going off the record. The time is 12:14 p m.

(Recess taken.)

THE VIDEOGRAPHER: We are back on the record. The time is 12:30 p m.

(Exhibit No. 6 was marked.)

BY MR. SAMSON:

Q. Mr. Morelli, you have in front of you what has been marked as Exhibit 6, in which says that it's a, "Sales Force Training REMS and Safe Use." Do you see that?

A. Yes, I do.

Q. And your name is down there, along with a Mr. Holman. Does that indicate you were either the authors of this slide set or was going to speak from it whenever it was in use this day?

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A. Yes. We were the authors of this slide set, and Kevin reported to me. He was a member of my team.

Q. Would this be a slide set and a presentation that you gave only once, so that you might remember the time and date, or would this have been given several times?

MR. DAVISON: Objection to form.

THE WITNESS: So I would say this is -- as it is right now, it may have been something we gave once or a couple times. But pieces of this were given multiple times.

BY MR. SAMSON:

Q. And as you were leafing through it, you saw, as I did, there's a C.A.R.E.S. Alliance portion near the end of it; correct?

A. That's right.

Q. And can you recall a time when you gave the "Sales Force Training REMS and Safe Use," and specifically added a C.A.R.E.S. Alliance piece to it for one reason or another?

A. Yes.

Q. When was that, and what was the event?

A. So when -- when -- I don't remember

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the event. But when the program was fully flushed out, fully ready to go, ready to launch, that's when we added the C.A.R.E.S. Alliance. That was after the REMS and the Exalgo, launch of Exalgo.

Q. Okay. And that date, launch of Exalgo, 2010; if you recall?

A. I don't recall. I don't recall.

Q. Okay. I think we may run into it.

A. Yeah. Yeah.

Q. In a numbered form.

And when Exalgo launched in 2010, it was a Covidien/Mallinckrodt-branded analgesic?

A. Yes.

Q. And an opioid?

A. Yes.

Q. Extended-release hydromorphone?

A. Yes.

Q. And was the OROS delivery system that it was in, the way in which it became an extended release instead of an immediate release?

A. Yes.

Q. And that was because the OROS system created a hard shell capsule, not like a contact, but something that was difficult to bite through at least; correct?

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MR. DAVISON: Objection to form.

THE WITNESS: Yes, there's some data to indicate it was quite hard to bite through.

BY MR. SAMSON:

Q. And then what it would do is allow -- once it was swallowed and into the digestive tract, allow water to come in osmotically, which would then expel the drug through a tiny laser-drilled hole through the shell?

A. Yes.

Q. And some engineer figured out the diameter so that that push of essentially IR, immediate release, immediate activity, hydromorphone would be bled out over a long time?

A. Yes. It wasn't the pharmacokinetics of the molecule, it was the release kinetics from the capsule.

Q. Perfect. So all I need to ask you -- and I get the engineering explanation.

So the REMS were part of -- which is risk, evaluation, and mitigation strategy?

A. Right.

Q. And at that point those were required for extended-release opioids, like Exalgo was going to be, by the FDA?

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A. Correct.
Q. Immediate-release formations were not forced to do REMS by the DEA or the FDA --
A. It wouldn't be the DEA.
Q. -- until 2015; do you know?
A. I don't know the date, but it was later.
Q. It was after you left?
A. It was.
Q. And then C.A.R.E.S. Alliance came out in the same general time frame as the launch of Exalgo?
A. Slightly thereafter, I believe. But I don't know. Very close, yeah.
Q. Okay. And was the C.A.R.E.S. Alliance your baby, so to speak, from the initial concept, or was there a C.A.R.E.S. Alliance thought process going on at Mallinckrodt, and then you came and brought it to fruition?
A. No.
MR. DAVISON: Objection to form.
THE WITNESS: It didn't exist until I brought it to existence, yeah.
BY MR. SAMSON:
Q. Okay. And so you were basically the

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one who came up with that strategic vision and then did the tactical, as you earlier said, parts of putting it together, I'm assuming with other aid -- help from other people --
A. Absolutely.
Q. -- at Covidien?
A. Right.
Q. And one of the things that I've seen in C.A.R.E.S. documents is that the increase in use of opioids and resulting abuse, addiction, and deaths have led to a backlash against the use of prescription pain medicine and have adversely affected pain treatment for legitimate pain patients.
Was that a concept, in your understanding, why C.A.R.E.S. was something that needed to be done?
A. A huge --
MR. DAVISON: Objection to form.
THE WITNESS: -- hugely important concept.
BY MR. SAMSON:
Q. As a major manufacturer and seller and even distributor of opioids, Mallinckrodt stood to lose sales as a result of a, quote, backlash against the use of prescription pain medicine, end quote. Is that true?
A. I assume it could potentially be

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true. But I can tell you that was not any motivation of doing C.A.R.E.S. Alliance, was related to that whatsoever. That was not in my -- that was not in my pitch to Herb and, you know, the CEO and the CFO to get the money to do the program because, you know, we're going to lose scripts. That was not even in my thinking.
Q. Since you left sales long before that, that doesn't surprise me.
What was the pitch --
MR. DAVISON: Objection.
BY MR. SAMSON:
Q. -- for?
MR. DAVISON: Sorry. I apologize.
BY MR. SAMSON:
Q. What was the pitch to Herb -- and who was the CEO, Mr. Wright?
A. No, he was not the CEO. It was -- his name was Matt Harbaugh, H-a-r-b-a-u-g-h.
So the pitch was, if you look at slide, in essence -- these pages aren't numbered, but it's the -847 MK number, that ends in -847.
Q. And what does it --
A. It says, "A concern we all have."
Q. Okay.

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A. "A responsibility we share and a concern we all can champion."
Q. And that became a fairly frequent opening slide for C.A.R.E.S.?
A. It's part of the essence of C.A.R.E.S.
Q. Okay. And let me find it.
A. It's about the middle.
MS. GAFFNEY: They have the Bates number.
MR. SAMSON: I don't have them. That's the real problem when you print them without it.
THE WITNESS: You've got it.
MR. SAMSON: There it is. Bingo.
Q. So the concern that you were pitching to Mr. Neuman and Mr. Harbaugh was what?
A. We have a -- there's a big problem going on. We have a big problem going on in this country. Everybody needs to be aware of the problem, to understand what this problem is all about. That's the concern.
Q. Okay.
A. If you're not concerned about that, you need to be.
Q. And that --
A. Then there was --

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Q. What specific concern, the opioid use in the country?
A. Mainly deaths and addiction.
Q. Okay.
A. The two most serious outcomes of what can happen with opioids, if you don't do them right.
Q. Okay. And then "A responsibility we all share." What was the responsibility?
A. Responsibility is that -- is at two levels. One, we have a responsibility for our products, to ensure that the physicians have everything they need to use them safely and appropriately. That's one level.
The second responsibility, as a member of the industry who sells opioids, we have a responsibility to try to help others do the same thing for their products.
Q. Okay.
A. And then --
Q. Go ahead. And then what is, "The cause that we all can champion"?
A. The cause is to actually try to do something about it.
Q. And that was the steps you took to establish the C.A.R.E.S. Alliance?

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A. Yes.
Q. And the materials in the C.A.R.E.S. Alliance?
A. Right.
Q. And that was in connection, or at least temporal connection, with the launch of Exalgo; correct?
A. Correct.
MR. DAVISON: Objection.
BY MR. SAMSON:
Q. And did you believe that Exalgo, when it was launched, was less susceptible to abuse due to its ORO system than ordinary, for example, ER Oxycontin?
A. I don't believe we had head-to-head kind of comparison data to indicate that. I think we had -- what I believe we did, as I remember, we just went forward with the assumption that it could be abused, and operated on that assumption. In other words, plan for the worst, hope for the best.
But we weren't going to mitigate what we were doing because we had a capsule that was kind of hard to chew. We weren't going to back off because, oh, it's hard to chew. No. We were going to do -- play it straight --

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Q. Okay.
A. -- in terms of the REMS. The Exalgo -- C.A.R.E.S. Alliance had nothing to do with Exalgo per se. But that was the REMS.
Q. Okay. And there's attached to -- was there a strategic commercial aspect to your identification of the C.A.R.E.S. Alliance strategy that you gave to Mr. Neuman and Mr. Harbaugh as well?
A. Yes, it is.
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. Okay. And if you will turn to --
A. It's the umbrella slide.
Q. That's it?
A. Yeah.
Q. Yeah.
A. This is a strategic map, that's what this is, the slide.
Q. And it's called, "The C.A.R.E.S. Alliance" on top?
A. That's correct. That's correct.
Q. And I take it, this is an Art Morelli designed document?
A. Me and my team.
Q. Okay. And where you -- if you see

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basically, as I'm reading this document, it is moving the company from "R," across to the right to "2B"?
A. Where we are to where we want to be.
Q. That's what I was taking from it, but I don't know if there was some other --
A. With respect to this particular aspect of the business.
Q. Correct.
A. Yeah.
Q. And this aspect of the business is the opioid pain space?
A. Correct.
Q. And we see Exalgo is in the first step, if -- if -- the arrows or arcs up above, on the baseline of the big portion of the circle, are those meant to be steps? The --
A. So the big arc is kind of the overall strategy.
Q. Correct.
A. The sub arcs are kind of the sequential steps in making the big leap. Because the big leap is too big to leap in one step. You have got to break it into three steps. So that was the thinking there.
Remember, this is a concept slide. This is

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a concept slide. And the fact that there are products listed underneath there is illustrative as to where our products -- because, remember, we have to make sure our products are used safely, to the degree we can, how they fit against the strategy.
Q. Do you believe that you took this slide or an earlier version of it with or without C.A.R.E.S. Alliance language to your pitch of Mr. Neuman and Mr. Harbaugh?
A. I think it was an earlier version. It may have been an earlier version.
Q. Certainly the concept --
A. The concept, yes.
Q. -- would have been part of your pitch to them?
A. Right.
Q. Correct?
A. Right.
Q. And so where we are -- I mean, the two -- I don't know what OTCF -- or OTFC means, over -- if the "C" was removed, it would be over-the-counter something.
A. I don't recall. I don't recall.
Q. But Exalgo we certainly see?
A. Right.

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Q. And then I meant -- I recognize Ruby, Zircon?
A. Those are R&D products.
Q. Exactly. Those were in reasonable doubt still?
A. But opioids.
Q. Yes. And then PENNSAID was intravenous acetomorphine?
A. No. PENNSAID was a topical nonsteroidal for knee pain. Knee pain.
Q. Okay. Methadone was existing as a generic --
A. A generic, yeah.
Q. -- for Mallinckrodt; correct?
A. Right. But not -- not an analgesic. It was addiction maintenance, methadone.
Q. But methadone --
A. It's the same methadone.
Q. But methadone itself has analgesic --
A. Oh, yeah.
Q. -- properties?
A. Absolutely.
Q. But you guys were selling it more for its --
A. Abuse --

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Q. -- abuse treatment --
MR. DAVISON: Let him finish the question.
BY MR. SAMSON:
Q. -- treatment place; right?
MR. DAVISON: Objection to form.
THE WITNESS: Right.
BY MR. SAMSON:
Q. And then back to your old land of imaging. That was going to try and build the brand; right?
A. Right. That was -- I just included the products there to show applicability across the product range. If we were known for this ability, you know.
Q. Okay. And then the one that Exalgo is completely -- or most visually related to is the arc of demonstrating REMS excellence?
A. Correct.
Q. And that was something you were already about, because you were working with the Exalgo REMS?
A. Correct.
Q. And then what is -- is the "highly compliant," are those prescribers, or what?
A. No. That's a company.

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Q. Okay. So that's you?
A. Company attribute that we wanted to be recognized for. And we would get there by demonstrating excellence with REMS.
Q. Okay.
A. That was the thinking there.
Q. And then PENNSAID, methadone, imaging and Fentanyl Patch are in the next narrow rectangle. And under that arc is, "Develop and launch C.A.R.E.S. Alliance," which I'm not sure I see a lot of connection between launching C.A.R.E.S. Alliance with imaging, say.
MR. DAVISON: Objection to form.
THE WITNESS: It was just a way to -- it probably really doesn't fit that much. It's just a way to try to create the idea that this was a broad, inclusive kind of effort that could apply to various product lines, if we were recognized as a company that's doing the right thing.
BY MR. SAMSON:
Q. Okay. And the arc in that is, "Develop and launch C.A.R.E.S. Alliance"; correct?
A. Right.
Q. Which is devoting resources to getting a really accurate message about opioids

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across to everybody in the chain, other manufacturers, prescribing physicians, hospital groups that might be involved in the use of opioids, and patients and their caregivers, like individual caregivers at home, not -- not prescribers?
MR. DAVISON: Objection to form.
THE WITNESS: Ultimately, yes. But it takes a while to get there.
BY MR. SAMSON:
Q. Okay. Well, I take it that with your wisdom in industry, you didn't pitch them at a meeting and tell them we're going to have this in two months?
A. No.
Q. Okay. So that's that step. And then that gets to be -- is this a recognition of status of Mallinckrodt in the -- in the strategy to be recognized as trailblazers, by that end of that second arc?
A. Right.
Q. Okay. And then "Partner and Publish," that is to get outsiders within the space, either prescribers, researchers, et cetera, to publish favorably about Mallinckrodt --
A. No. No.

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MR. DAVISON: Objection.
BY MR. SAMSON:
Q. What is it?
A. That was to publish mainly the results of our programs, if there were a publication here that is a scientific document to show that they are achieving what we intended them to achieve.
Q. Okay.
A. And "partner" would be partner with other outside groups outside of Mallinckrodt on some of these initiatives.
Q. Of these other pharmaceutical houses?
A. It could be anybody. It could be a pharmaceutical company. It could be a pain society. It could be anything like that.
Q. And then Ruby, Zercon, et cetera, are put there in that little box, I'm assuming, because they were a ways away?
A. They were a ways away, yeah.
Q. And so they would be hopefully profiting by all these things when they were ready to come out?
A. Right.
Q. And then if the strategic plan was realized and Mallinckrodt got to where it wanted to

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be, then it would be recognized first as a leader in the science of safety?
A. Right.
Q. And as you pointed out earlier, the science of safety principles have existed at least since nuclear reactors were developed. This would be a leader in the science of prescription safety; is that a fair addition?
A. Yes.
Q. And that --
A. Mainly opioid. Yeah.
Q. And that would lead to better patient outcomes; correct?
A. Right.
Q. And that would lead to Mallinckrodt being recognized as a leader in pain?
A. Right.
Q. And that would -- strike that.
Did you tell leadership that would be a good position financially and otherwise for us to achieve?
A. That would be a good position for us to achieve in light of the massive problem that exists in society. Someone -- it was the problem, my analysis, my belief at the time, the problem was screaming for leadership. And the FDA needed a

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friend.
Because we were going to be that friend, and we were going to be that leader. That was my vision.
Q. And if, in fact, all that came true, you would be a -- a respected and, in quotes, good member of big pharma?
A. I think so.
Q. Okay. I mean, that's -- that's what the goal was?
A. Absolutely.
Q. That would be a marketing -- huge marketing plus?
A. Right.
MR. DAVISON: Objection to form.
THE WITNESS: I'd say a huge plus. A plus. Don't confine it to marketing. It's a huge plus.
BY MR. SAMSON:
Q. It would be --
A. It would cascade across the organization, yeah.
Q. Okay. And it certainly wouldn't do any harm for marketing if one occupied that position?
A. It shouldn't.
MR. DAVISON: Objection to form.
///

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BY MR. SAMSON:
Q. And this plan, from what you've said before, seems not to include directly generics?
A. Right. Remember, the C.A.R.E.S. Alliance is not a product program. I was putting this lower line there to show how it would be applicable -- of where its applicability would be just in reference to our products, but in reference to other products, too. Because it's the principles that are important, not the products.
But this was a general presentation. So this is an illustrative overview of what we're going to try to do and where it is potentially applicable.
Q. Okay. Let me ask you to turn back now to the "Sales Force Training in REMS and Safe Use."
A. Okay.
Q. And let me ask a couple of questions. I missed my little notes here.
A. Okay.
Q. As we talked about earlier, the C.A.R.E.S. Alliance part of the strategy was launched at Pain Week of 2010?
A. Right.
Q. Were you there?

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A. I was there.
Q. And Covidien owned the trademark and basically the group; true?
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. C.A.R.E.S. Alliance?
A. Yes. Yes. Yes.
Q. Was that your idea to have it be a Covidien owned for use in the strategic plan?
A. At the beginning, yes. But not ultimately. I was hoping it would involve others, also.
Q. Okay.
A. Yeah.
Q. And then were there members of C.A.R.E.S., since it's called an alliance? Or what did you, Art Morelli, call them?
MR. DAVISON: Objection to form.
THE WITNESS: The goal was to get members, other members besides -- besides -- besides Mallinckrodt, other members. While I was there, we didn't. We talked about people-to-people organizations about being a member, and endorsing this, and endorsing that. But to become a -- you know, to help support it financially is another

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thing.
So we had a lot of support in word and spirit, but not much support financially, which -- you know how it goes.
BY MR. SAMSON:
Q. And did you reach out to outfits like the American Academy of Pain Management?
A. We did, yeah.
Q. That was someone who you pitched on membership?
A. Right.
Q. Were they one of the ones who weren't willing to -- I mean, I can't imagine that this wasn't in step with their ideas; right?
A. We had some discussion.
MR. DAVISON: Objection to form.
THE WITNESS: We had some discussions with them, and they were supportive of what we were trying to accomplish. But they are an organization that needs to raise money, too, through their memberships and their various activities. So they are not really in a position to be able to give some of that money away.
But we had a good working relationship. Phil Saigh, who was the executive director of the

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APPM, and I had a good working relationship. Actually my ex-student. But he's a good guy. They are in Chicago.
BY MR. SAMSON:
Q. And were they supported by Mallinckrodt financially?
A. I don't know.
Q. Okay. All of the taking -- you said that sometimes, like a management meeting or orthopedic meeting convention, Mallinckrodt would take a large booth, and then would have a small booth, or a portion of the booth put over to your uses for C.A.R.E.S. Alliance?
A. Right. With a curtain -- the curtain separator, and it would be Medical Affairs portion of that small booth, and then a patient and product safety portion of that small booth.
Q. And when Mallinckrodt purchases such convention space, that's financial support for whatever the organization is --
A. It is.
Q. -- putting it out?
A. It is.
MR. DAVISON: Objection to form.
///

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BY MR. SAMSON:
Q. Any others who you require pitching -- or require -- remember pitching about C.A.R.E.S. Alliance, other than the AAPM?
A. Pitching, not specifically. But I remember presentations to other entities about what we were doing to inform them about what we were doing, and one of those was the FDA.
Q. I take it, the FDA did not offer to buy a membership?
MR. DAVISON: Objection.
THE WITNESS: They did not.
BY MR. SAMSON:
Q. Anyone else who you recall making a presentation to -- the FDA one was not to induce interest in joining the Alliance?
A. No.
Q. Anyone else who the interest was getting them interested in joining the Alliance?
A. I don't recall any others, no.
Q. So the American Academy of Pain Management, would you say it's a fair description, that being an organization that was focused on keeping opioids available for patients with pain?
MR. DAVISON: Objection to form.

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THE WITNESS: No, not at all.
BY MR. SAMSON:
Q. Okay. What is wrong with that?
A. I think they were focused on best practices in pain management.
Q. Okay. And that was Dr. Webster's outfit?
A. Not his outfit, no. He was an officer in it.
Q. A member?
A. For awhile. That was a rotating kind of thing. Other physicians rotate through that position. But, yes, he was involved with the AAPM, as were other physicians that we worked with.
Q. And do you believe that the AAPM was generally oriented against stricter regulations or restrictions on opioid use for chronic pain?
MR. DAVISON: Objection to form.
THE WITNESS: I have no idea what their political or legislative, you know, plans were.
BY MR. SAMSON:
Q. Okay. But AAPM, nor anyone else, ever gave any money to support the goals and work of C.A.R.E.S. other than Mallinckrodt?
A. To the best of my knowledge, yes.

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Q. While you were there?
A. Yeah.
Q. Let's turn back to Exhibit 6.
A. Okay.
Q. And I'm going to apologize ahead of time. But if you will look, there's a car --
A. Oh, yeah, the car slide.
Q. Yeah.
A. Okay.
Q. You gave this presentation at least once?
A. I created this slide, and I gave this presentation.
Q. Okay. I don't quite understand it.
A. Most people don't.
Q. Okay. Can you give me the -- what you would have said, if I was sitting in an audience at -- getting sales force training for REMS and safe use.
MR. DAVISON: Objection to form.
THE WITNESS: So this is a concept slide intended to reinforce to our sales force and marketing people why it is so important that their physicians be fully trained on the safe use of Exalgo. So I was trying to create something that

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related to what they did in their daily lives.
So I broke it into three levels. A Honda, a Corvette, and a Ferrari. Most people relate to cars. Right. Because I know everyone in that audience drove a car.
So it -- the story went like this: How many people in the audience have a driver's license? All the hands went up.
How many people feel comfortable driving a Honda? All the hands went up.
You need a lot of specialized training to drive a Honda beyond just being a licensed driver? No.
Okay. What if you were driving a Corvette, that's a high-powered performance car. Don't you think it would be a good idea if you had a little more advanced training if you're driving a Corvette around? Everyone said, yeah, yeah, I would probably need a little training. Sure.
So then what if you were driving a top-of-the-line Ferrari, and you wanted to fully exploit the performability of that car, you're going to need some training, some serious training, or you will probably kill yourself.
So the analogy here is, APAP, opioid combo

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products are the Hondas of the pain world, in terms of complexity of use. They still have a lot of problems associated with them. Your Honda -- you can still kill yourself in a Honda, but most people know how to use those drugs.

So if you go in to start to train doctors on how to use those products, you're not going to get anywhere because they already know how to use them, more or less.

BY MR. SAMSON:

Q. Can I interrupt for a second?

A. Sure.

Q. Having been in the pharma business, don't you think that it's more accurate that the doctors think they know how to use them more or less, because they have been using them for years and they have their own opinions on them?

A. I think that would be --

MR. DAVISON: Objection to form.

THE WITNESS: -- accurate. Doctors think they know everything. But to try to get their attention on something they are really confident, they use every day, and they are not getting a lot of problems that they can see, it's going to be difficult. I don't think impossible. And I wouldn't

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say they couldn't benefit from some additional, you know, updating. Absolutely. But for the purposes of this one, I was trying to create a continuum.

So, you know, you have long-acting opioids, Opana, Oxycontin, Oxycontin, et cetera. Those are more -- those are more high-performance products with more risk. You can kill yourself easier, like in a Corvette. So you need to know how to use these things. You just don't throw 'em out there and prescribe 'em. You need more diligence.

And then we have Exalgo, which is a brand-new product that no one has ever used before. It's a single entity opioid that's really potent, more potent than these, Opana and oxy. So you need more specialized training so that you don't run off the road at 150 miles an hour.

That was the analogy I was trying to create. Because what I was trying to do was get buy-in from everybody of why we need to go beyond -- above and beyond the call of duty on the Exalgo REMS.

BY MR. SAMSON:

Q. Okay. Why is it -- the APAP combos, are those -- whatever the opioid is involved, is that an immediate release, in your diagraming here?

MR. DAVISON: Objection to form.

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THE WITNESS: It is. It's a Vicodin-like product, yeah.

BY MR. SAMSON:

Q. And then Opana and Oxycontin were both -- Oxycontin, by the time you were giving this presentation, was mostly in extended release, although still available in immediate release?

A. Right. And no -- no nonopioid component to it. That's very critical, actually.

Q. Okay. And Opana, what molecule is that?

A. Oxymorphone.

Q. And Exalgo was hydromorphone?

A. Hydromorphone.

Q. And Opana, extended release?

A. Yes.

Q. Okay. So why -- what's the step up? You were talking about risk and need for more training from the immediate release APAP combo to Opana/Oxycontin?

MR. DAVISON: Objection to form.

BY MR. SAMSON:

Q. Extended release?

A. It's more opioid. It's used for a longer period of time. All those factors increase

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risk and potential harm to patients.

Q. Okay. And then on the risk side, Opana was -- had risk deterrent features, not to the FDA's level of allowing it to be abuse deterrent, resistant labeling; true?

MR. DAVISON: Objection to form.

BY MR. SAMSON:

Q. But it had some built-in attempts to reduce risk from it; am I right?

MR. DAVISON: Objection to form.

THE WITNESS: I believe you're right.

BY MR. SAMSON:

Q. Okay. And certainly Exalgo did; correct?

A. No. Not according to the FDA, no.

Q. And, in fact, they never did approve -- is it ADF or ADR labeling?

A. ADF.

Q. ADF?

A. Yeah.

Q. You never got to that; correct?

A. Not while I was there, no.

Q. So higher risk, more training; lower risk, less training for sales --

A. So there's a risk.

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MR. DAVISON: Objection to form.
THE WITNESS: There's a risk difference here. There's also a familiarity difference. So drugs that physicians are very familiar with, moderately familiar with, unfamiliar with.
MR. SAMSON: Okay.
MR. DAVISON: Mark, we have been going another 40 minutes. We're almost ready for lunch.
MR. SAMSON: Sure. Let's do it.
THE VIDEOGRAPHER: Going off the record. The time is 1:11 p.m.
(Lunch recess taken at 1:11 p m.)
--o0o--

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AFTERNOON SESSION 1:54 P.M.
--o0o--
THE VIDEOGRAPHER: We are back on the record. The time is 1:54 p m.
BY MR. SAMSON:
Q. Hi, Mr. Morelli.
A. Hello.
Q. Remember all the stuff we talked about before the deposition, about how depositions go on? No changes; okay?
A. Correct.
Q. Good. REMS were required by the FDA for Exalgo; true?
A. True.
Q. Were the EEIFs that you guys put together, the essential -- Exalgo essential information forms --
A. Right.
Q. -- were those required by the FDA or was that a Mallinckrodt decision?
A. I believe it was required.
Q. Okay. And what were the EEIFs meant to do in terms of the FDA's program for REMS and EEIFs?
MR. DAVISON: Objection to form.

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THE WITNESS: It was meant to create a measurable, call it a metric, that physicians had read the REMS and understood the REMS and really understood the risks inherent with the product.
(Exhibit No. 7 was marked.)
BY MR. SAMSON:
Q. And let me ask you to turn to Exhibit 7, which is an email list -- or a couple of e-mails back and forth, and then a longer list of Ohio doctors.
A. Right.
Q. Have you had a chance to familiarize yourself with that?
A. I remember this campaign. I don't remember this email, but I remember this campaign, yeah.
Q. Okay. And down at the bottom -- I think it's -- is it Mr. Meyer or Ms. Meyer?
A. Jay Meyer is a man, yeah.
Q. Okay. Mr. Meyer says that he promised you that he would get all the listed docs EEIFs submitted?
A. Correct.
Q. And if you will look down under the "All," is where he -- in the middle of the page.

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A. Oh, yes. Yes.
Q. He had a lengthy conversation with Art, you; correct?
A. Correct.
Q. And Preston, who is --
A. Preston -- Preston Walker, who worked for me.
Q. (Reading) As a result, I have guaranteed we will obtain a completed EEIF from all -- "all" in caps -- physicians listed with the exception of Dr. Naum (end of reading).
My first question is, do you have any memory of why Dr. Naum would not be part of this seemingly global program?
A. I have no idea.
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. Do you have any reason to remember how these listed physicians were selected?
A. Oh, yeah. These physicians were physicians who were Exalgo prescribers but had not completed an EEIF.
Q. Okay. And is the fact that they are all in Ohio simply because that was Mr. Meyer's area?

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A. Yes.
Q. And then in his email to you, he says:
(Reading) The following physicians are speakers, so I am guessing you can have the EEIF completed relatively quickly (end of reading).
And then a list of four physicians.
MR. DAVISON: Objection to form.
THE WITNESS: Okay.
BY MR. SAMSON:
Q. And do you recall any of those four listed physicians?
A. I do not.
Q. Okay. He says they are speakers. So why -- knowing how Covidien works, why would speakers be expected by Mr. Meyer to be guessing that those guys would complete their EEIFs relatively quickly?
A. You would think so.
MR. DAVISON: Objection to form.
THE WITNESS: You would think so.
BY MR. SAMSON:
Q. Because?
A. Well, they are speaking on the product. So if they are speaking on the product,

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they have to do -- they should complete the basics regarding the product safety more than ever.
Q. And any explanation that you recall for why these four doctors wouldn't do that?
MR. DAVISON: Objection to form.
THE WITNESS: No. More than likely, it's inertia.
BY MR. SAMSON:
Q. When they are listed as speakers, I think you've told me that Medical Affairs didn't pay for speakers; correct?
A. Correct.
MR. DAVISON: Objection.
BY MR. SAMSON:
Q. Were speakers compensated by Mallinckrodt out of some other budget?
MR. DAVISON: Objection to form.
THE WITNESS: Yes.
BY MR. SAMSON:
Q. And which department was that?
A. Commercial.
Q. Okay. And do you have an idea of -- if I, as a speaker, go to a pain management meeting and am there sponsored by Covidien, what would I get as a speaker?

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MR. DAVISON: Objection.
BY MR. SAMSON:
Q. If you have any idea.
A. It really depends. I don't know, because I didn't deal with this. But even if I had, I wouldn't have remembered the number.
But it's -- it's -- there's certain guidelines of what -- you can't, you know, pay them $100,000 to give a one-hour talk. I'm being very exaggerating here. There's a fair market value kind of calculation.
There's various organizations, more so now than then -- this is almost ten years ago -- that require that the fees not be exorbitant, and in line with other things that the doctor may be doing. So, yeah.
Q. And those recent restrictions, or the ones that might have been in place, were those industry guidelines put together, or were those FDA or some other entity guidelines?
MR. DAVISON: Objection to form.
THE WITNESS: Not FDA. Those were industry and Covidien's guidelines, which may or may not -- which likely are stricter than the industry guidelines. Because the industry guidelines are just

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that, guidelines. Ours were firm lines, you know.
BY MR. SAMSON:
Q. That essentially set limit of the price one could pay a speaker to talk about a Covidien product at a meeting, based on probably how long it was, how long the presentation was?
A. No.
MR. DAVISON: Objection to form.
THE WITNESS: No. Based on a presentation. They are all about the same length. Yeah.
(Exhibit No. 9 was marked.)
BY MR. SAMSON:
Q. Let's move to, out of order, Exhibit 9.
A. Exhibit 9.
MR. DAVISON: Do we know the Bates number? I am not sure which ones we have. Yeah, I don't have that one.
MR. MAEROWITZ: We have Exhibit 8 and 7.
MR. SAMSON: It would have been 6 originally.
MS. GAFFNEY: Which document are you looking at?
MR. SAMSON: It's a one-pager.
Go off.

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THE VIDEOGRAPHER: We are going off the record. The time is 2:03 p.m.
(Discussion held off the record.)
THE VIDEOGRAPHER: We are back on the record. The time is 2:04 p.m.
BY MR. SAMSON:
Q. All right. Mr. Morelli, this one is another one about -- the "Re" line is EEIFs; correct?
A. Right.
Q. And then you're the person at the top responding to the email at the bottom; correct?
A. Correct.
Q. And you wrote:
(Reading) That's correct. If they have not written a script, we don't need the EEIF. We already have 500-plus from non-Exalgo writers. They don't count (end of reading).
Did I read that correctly?
A. You did.
Q. And Exalgo writers are people who have written a prescription for Exalgo?
A. Correct.
Q. Why -- I mean, the EEIFs are a safety tool; correct?

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A. For Exalgo.
Q. And why do the nonprescribers reading of the safety information about Exalgo not count?
MR. DAVISON: Objection to form.
THE WITNESS: It doesn't count because the direction from the FDA was to obtain compliance with this -- with what's called an attestation that they read the material. If a physician has no intention of reading the material, is not interested in the product, they have no reason to do the attestation.
So physicians are very sensitive about signing their names to things --
BY MR. SAMSON:
Q. Okay. But --
A. -- and the reps want to get signatures. So you have those things colliding.
Q. Well -- and what I don't understand, it's a safety tool; correct?
A. For Exalgo.
Q. For Exalgo?
A. Yeah.
Q. And the fact that I haven't written a prescription to date doesn't really knock me out of consideration as writing a prescription for it in the future; correct?

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A. Oh, absolutely. A physician can prescribe whenever they feel like it. But it may be that the doctor has no intention. If a doctor has an intention, read it, fill it out. Absolutely.
Q. But you guys weren't even going to take them.
A. Well, we took them. It's just that we're -- they are not going to count in the tally that the FDA is interested in, which is our prescribers.
So if we had -- if we have a thousand prescribers, and we have 800 completed EEIFs, that will make them happy. But a thousand would be better. But if we have 800 out of a thousand -- and, oh, we have 500 other doctors who are not even involved with Exalgo, they are not going to be impressed by that. They want us to do things according to the REMS.
Q. And so not counting didn't count against your, Mallinckrodt's, Exalgo percentage of prescribing doctors who had actually filled out an EEIF?
A. Right.
Q. And that was the only number that you guys were concerned about?

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A. But I'm like you, if a hundred other people want to read the safety information on Exalgo and fill out the form, I'm okay with it. But it's just not going to count against the metric, you know.
Q. But it does count to the general safety awareness of the possible prescriber to have read the EEIF?
A. You could look at it that way, yeah.
(Exhibit No. 8 was marked.)
BY MR. SAMSON:
Q. This will be No. 8. I think you already have it, Mr. Morelli.
A. I do. I think I do. Yeah, this one.
Q. Before we get to the details of Exhibit 8, REMS and EEIM were thought by the FDA for extended release opiates to be -- in 2011 to be important safety tools?
MR. DAVISON: Objection to form.
THE WITNESS: An important metric, amongst other metrics, in terms of educating physicians on the risks.
BY MR. SAMSON:
Q. And the -- the goal of educating physicians on the risk is to increase the safety of the prescribers for whatever medications REMS and

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EEIFs are involved; true?
MR. DAVISON: Objection to form.
THE WITNESS: To increase the knowledge of the prescribers on safe use practices with respect to Exalgo that we are recommending that they employ.
BY MR. SAMSON:
Q. And the opposite of that, not reading a REMS, not filling out -- reading or filling out an EEIF, is prescription being written with less information?
A. Exactly.
MR. DAVISON: Objection.
BY MR. SAMSON:
Q. And that's, in the way you view the world, I think, less safe than an informed prescriber writing a prescription of any of the opioids?
MR. DAVISON: Objection.
THE WITNESS: Yes.
BY MR. SAMSON:
Q. And was there -- was the FDA, did it ban REMS or EEIFs for generic immediate release --
MR. DAVISON: Object.
BY MR. SAMSON:
Q. -- opioids?
MR. DAVISON: Objection to form.

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THE WITNESS: Did it ban?
MR. SAMSON: Yes.
THE WITNESS: No, not that I know. Why would they do that?
BY MR. SAMSON:
Q. I mean, obviously, these are informational tools.
A. Right.
Q. Which are good for any drug, whether it be a multiple sclerosis drug or an opioid; true?
A. Right. But they are generally not interchangeable. They are product specific.
Q. Oh, that -- I understand that. But just in -- it's not just an opioid tool, it's a wider-spread tool for any prescribed medication?
A. It's -- it's an adaptable tool that could be adapted to any medication.
Q. And there wasn't any ban from the FDA on producing REMS or producing EEIFs on generic opioids in 2011; true?
MR. DAVISON: Objection to form.
THE WITNESS: So REMS is regulation. REMS is regulatory. So REMS are imposed or required. By "imposed or required," I mean mandated by the agency at their discretion. And if they so deem that

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to be necessary, we have to implement it.
BY MR. SAMSON:
Q. I understand. But in generics, especially -- except not all generics, but immediate release --
A. Right.
Q. -- they weren't required until 2018; correct?
A. Right.
MR. DAVISON: Objection to form.
THE WITNESS: And even branded immediate release were not required. Because the Agency's opinion was that they were less risky because they were older products, that doctors were more familiar with the risks, and they had been using for years. So it didn't happen till later, till they realized it's all one big problem.
BY MR. SAMSON:
Q. And there was nothing to stop Mallinckrodt, if it realized quicker than the FDA that it's all one big problem, to add educational materials concerning its immediate -- immediate-release generic opioids?
MR. DAVISON: Objection to form.
THE WITNESS: True. But we went even bigger

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than that. That would have been a big step. We went way bigger than that. We did the C.A.R.E.S. Alliance for all opioids, whether they were ours, generics, branded, whoever -- whomever, whatever, to enforce the principles, the principles of good pain management, especially for chronic pain, and safe medication uses, and the concept of protecting patients from harm.
So we went bigger than that. That's why you got that big umbrella.
BY MR. SAMSON:
Q. And in going bigger, did you make sure that physicians who were prescribing Mallinckrodt immediate-release opioids took advantage of those programs, or did you simply have it out there available?
MR. DAVISON: Objection to form.
THE WITNESS: We had it out there available. And, quite frankly, we have no idea who's prescribing the generics, because we don't -- we don't call on them and detail doctors on generics and try and -- and inform them about the availability of generics that we produce.
That's not how generic works. It's done at the pharmacy. It's substituted at the pharmacy, no

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matter what the doctor prescribes. So we don't really know who would be a prescriber or not a prescriber. That was my state of the -- maybe they know now because they have better data now, but that was my understanding of it.
BY MR. SAMSON:
Q. And no one ever considered doing a mailing to specialties that were involved in opioids, like anesthesia, pain management, et cetera, to inform them of similar information that you were putting out for Exalgo through the REMS and the EEIFs, for immediate-release generics that Mallinckrodt sold?
MR. DAVISON: Objection to form.
THE WITNESS: We did a ton of direct-to-physician and direct-to-pharmacy communications by mailing and by -- whatever they call it, fax, mass -- mass faxing on Exalgo. We went beyond what we had to do, as required there. Like we did it multiple times. But we would have to send it to every physician in the United States. That's over 1.1 million DEA registrants.
BY MR. SAMSON:
Q. My question isn't what you would have had to do. You would have known, with your position

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at Mallinckrodt, about in the REMS world, correct, if Mallinckrodt was interested in increasing that program to include prescribers of immediately released generic opioids; true?
MR. DAVISON: Objection to form.
THE WITNESS: If they were going to do something, I would probably know about it, right.
BY MR. SAMSON:
Q. And you never --
A. I did not know about it. I did not know about it.
Q. We're getting back to conversation, and I --
A. Okay.
Q. And I enjoy it as much as you do, but we have to stay in the setting in which we find ourselves.
You didn't know about it because nobody asked you for your input on that front; correct?
MR. DAVISON: Objection to form.
THE WITNESS: Not that I recall. They didn't ask for my input.
BY MR. SAMSON:
Q. Exhibit 8 -- sorry to have gotten off track -- this is an email from Mr. Keith Huels,

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May 17th, 2011. So within a year or a month or so of when you joined Medical Affairs?
A. Uh-huh.
Q. And its subject line is, "Promo Speaker's Budget."
A. Right.
Q. What are promo speakers?
A. A speaker who gives promotional talks.
Q. And I'm going to end that sentence with, for Covidien products; is that the correct ending or --
A. No. No.
Q. -- not?
MR. DAVISON: Objection.
THE WITNESS: Or Exalgo. Or PENNSAID, actually.
BY MR. SAMSON:
Q. Either/or?
A. Yes.
Q. And forgive me if I am confused, but I thought promo speakers weren't out of Medical Affairs budget or --
A. They were not. But we had oversight. We had Medical Affairs oversight on the budget as a

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check that there were not irregularities in who was getting paid what.
Q. Now, as I -- and then there's attached a long list of people or entities more -- some entities, some individual names?
A. Correct.
Q. And if you look back to the last page, there's total invoices -- total invoices are $1,852,858, up at the very top left.
A. Yeah.
Q. And then invoices and accruals are $1,113,305?
A. Right.
Q. And then there's a Medical Affairs accrual, hyphen, Selva, April, of 144,000?
A. Okay.
Q. Do you remember any of those?
A. No. But I remember the overall processes.
Q. And what was the budget that would go to promotion -- promo speakers in a full fiscal year when were you there?
A. I have no idea. I don't remember.
Q. Okay.
A. Yeah.

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Q. Let me go through -- ask you to go through -- do you remember who Selva Group was?
A. Selva was a -- I don't actually know. I remember the name, that's all.
Q. Okay.
A. They had to do with speakers, though.
Q. Okay. Are some of these ones that appear again and again, like Selva, Advanced Health -- and I'm assuming ME went further out to --
A. Yeah.
Q. -- in the title -- were these bureaus or --
A. I think they were bureaus. I think they were bureaus or scheduling entities or scheduling -- scheduling entities for the speakers.
Q. And Paragon Rx International?
A. Yeah, that was -- that was mine. That was all under my budget.
Q. And what --
A. Paragon Rx, you were going to ask me? I'm sorry.
Q. What are they? What is it?
A. They're -- they're a consulting company that I use for the Rx FMEA and other consulting on REMS.

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Q. And are they physicians or nonphysicians or both?
A. They are a mix of physicians, pharmacists, and Pharm.Ds, and civilians.
Q. And they can supply you with speakers --
A. No, not speakers. Not speakers. The Rx FMEA and REMS -- REMS. They are a company that specialized in REMS creation and REMS implementation.
Q. Why are they appearing on the promo speakers' budget lines, then?
MR. DAVISON: Objection to form.
THE WITNESS: I don't think it's a -- I think that's just a heading of the email. They had nothing to do with promo speakers, I can tell you that.
BY MR. SAMSON:
Q. Okay. Did Selva Group have to do with promo speakers?
A. I believe they did, yeah.
Q. How about Advanced Health ME, whatever that's short for, do you recall --
A. I don't recall them.
Q. Okay. So they might have been promo speakers?

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MR. DAVISON: Objection to form.
THE WITNESS: I -- I don't know.
BY MR. SAMSON:
Q. Okay. Well, as far as Paragon Rx International, you've told me that those -- those amounts are probably them being paid to contribute to the REMS and the Rx risk assessment?
A. Yeah. Yeah. I can guarantee that that's the case.
Q. Okay. And then if you look on the next page, there's Schwartz MD?
A. No, that -- I don't know what that is.
Q. Okay. And Rosenblum, Stuart?
A. I have no idea.
Q. And Guernelli -- Guernelli?
A. I don't know. Sorry.
Q. And then the rest we have already talked about.
A. Yeah.
Q. And then the accrual balance, which you're a better businessman than me, I'm assuming these are amounts that the various listed entities have coming but haven't been paid yet?
A. Correct.

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Q. And do you recognize Reichman, Ronald P.?
A. No.
Q. How about Halley, Randall E.?
A. I do.
Q. What was Halley, Randall E.?
A. He is a physician that conducted clinical studies for us.
Q. Clinical studies of Exalgo?
A. Yeah.
Q. And what kind of clinical studies? Premarketing or post marketing?
A. I'm sorry. I'm going to have to correct my answer. I got him mixed up with another physician.
He did not, to the best of my knowledge, conduct clinical studies. He was a -- I think he was a speaker, actually. Yeah.
Q. Okay. And then Selva's, Victor Byrd?
A. Don't know.
Q. Sharon Idan -- or Idan, Sharon?
A. Don't know.
Q. George Spyropoulos?
A. Don't know.
Q. David Medunick?

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A. Don't know. Sorry.
Q. Any of the other personal names that follow there? Why don't you just -- to save us time, how about you scan the rest of the list --
A. I'm scanning, yes.
Q. -- and find any personal names --
A. I'm scanning.
Q. -- that you recognize or business names, if we haven't already talked about them.
A. Right.
Q. There's Randall Halley again.
A. No. The only name I recognize on here is Randall Halley.
Q. And did you tell me what you thought his role was? I know you told --
A. I think he was a speaker. I think he was a speaker. That's what I think.
Q. For Exalgo or --
A. For Exalgo.
Q. Okay. Let me ask you something I should have asked first.
You will see there's -- in the left-hand column, there are PVs and OVs. Does that mean anything to you as an ex-Covidien?
A. OV means nothing.

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PV is generally an abbreviation for pharmacovigilance. But it doesn't really fit in this case. So I don't know what it means here.
MR. SAMSON: 10, Sandy?
THE REPORTER: Yes, Exhibit 10.
(Exhibit No. 10 was marked.)
BY MR. SAMSON:
Q. Mr. Morelli, I will tell you, just to orient you, this is a series of emails about an expected release of a JAMA article on -- regarding that opioid deaths are higher with higher dosing patterns.
A. Okay.
(Witness reviewing document.)
A. Okay.
Q. Do you recall this study coming out?
A. No.
Q. Okay. Earlier we talked about the old per-need dosing patterns.
A. p.r.n.
Q. p.r.n., correct. And versus more regular dosing of, especially, extended-release opioids.
A. So do you want me to address what you just said, or what?

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Q. Yes.
A. So you can't --
MR. DAVISON: Objection to form.
THE WITNESS: You can't dose extended-release opioids on a p r n. basis. It's contraindicated. You dose them once a day or twice a day. That's it.
BY MR. SAMSON:
Q. And I was -- you and I are on the same page.
A. Yeah.
Q. On per need, the new regular dosing pattern went over to extended release use of opioids; correct?
MR. DAVISON: Objection to form.
THE WITNESS: I don't understand what you mean, "the new regular dosing pattern."
BY MR. SAMSON:
Q. Well, you --
A. Extended release -- let's take Exalgo as the example, is dose once a day. That's the only way it can be dosed.
Q. Correct.
A. Yeah.
Q. And ER Oxycontin is dosed twice a

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day?
A. Right. Right.
Q. There was a time when no opioids were dosed once or twice a day but, rather, when you have pain, ring your buzzer or tell me or take an immediate-release tablet; correct?
A. Yes, but --
MR. DAVISON: Objection to form.
THE WITNESS: -- none of those were extended-release opioids that were ever dosed on a p.r.n. basis.
BY MR. SAMSON:
Q. So this study was looking at what you and I had agreed on earlier was that the amount of opioid that patients received with regular dosing was generally higher than they received in a milligram equivalent, or whatever, from per need; true?
MR. DAVISON: Objection to form.
THE WITNESS: I -- I don't know. I don't know. It could have been higher. It could have been lower. It's based on patient need.
So Freddie gets his dose when Freddie requests his dose as opposed to the doctor saying it's every four hours or every six hours.
///

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BY MR. SAMSON:
Q. Well, how are you weighing in on what to do about this study if you didn't even read it?
MR. DAVISON: Objection to form.
THE WITNESS: Well, Nancy Stauder outlined what the study was generally about, just like you did. There's a huge overdose problem. So what she -- she's a communication person.
MR. SAMSON: Okay.
THE WITNESS: She was recommending the use of tools to aid physicians to prevent overdoses, no matter how they dose the products, their general methods.
And you can see there Covidien strongly supports the need for appropriate screening, prescribing, and use of all opioid medications. That's our position. Because of that need, we recently launched C.A.R.E.S. Alliance. This initiative provides a number of tools and programs to aid physicians, pharmacists, patients, and stakeholders.
Among the items available at C.A.R.E.S. Alliance are a urine drug screening guide, a patient prescriber expectations, responsibilities form, and a number of patient assessment tools.

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These are tools that are designed and had been validated to solve -- help solve this problem that this article is bringing out.
BY MR. SAMSON:
Q. Look at the first paragraph of her response, her draft message. Okay?
A. Okay.
Q. The bolded, in fact, "The article is attached for your awareness only."
A. Right.
Q. "You should not provide this to physicians, nor should you use it in proactive outreach."
A. Absolutely.
Q. And why is that?
A. Because it's Standard Operating Procedure that the sales organization cannot pick up some study, any study, that they want and use it in their -- in their sales activities unless that study has been approved for use by Medical Affairs. And this isn't even out yet.
Q. Is there any indication that they're going to ask you to approve it in this email string on this exhibit?
MR. DAVISON: Objection to form.

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THE WITNESS: I don't know. I don't -- I don't see that.
I see a draft message from a communications person to the field informing them that data is going to be released in JAMA, and nothing more. And if they get questions on it, or someone is concerned about the opioid problems, that rather than get in a debate whether the article is right, wrong, up or down, to refer that physician to the C.A.R.E.S. Alliance tools to prevent the problems that are highlighted in that article.
That's -- that's a responsive organization to data being released that shows problems.
BY MR. SAMSON:
Q. And you don't think that the findings of this study, because you never read it, showed problems with the very kinds of opioids that Mallinckrodt was selling?
MR. DAVISON: Objection to form.
THE WITNESS: Mark, no one denies there's problems. We know there's problems. If there weren't problems, we wouldn't have created the C.A.R.E.S. Alliance. That's a response of a responsible, concerned organization to provide tools that physicians can actually use in their practice

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with actual real patients to prevent some of this stuff or to help prevent some of this stuff.
BY MR. SAMSON:
Q. Are any of the C.A.R.E.S. Alliance tools to encourage the physician, perhaps, to think over whether or not this patient should be on extended-release opioids?
A. Absolutely. Be on opioids at all.
Q. Okay. Now, the letter to the sales force goes on that:
(Reading) If the doctor is willing to talk with you after you give the script -- that is the boldface above -- proceed based on previous guidance (end of reading).
Which I take it, is a kit that was dropped off concerning C.A.R.E.S.?
MR. DAVISON: Objection to form.
THE WITNESS: I don't know. It could be. It could be.
BY MR. SAMSON:
Q. Okay. (Reading) And then if the clinician persists in wanting to discuss the article, then they are given another bold point -- boldface

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response (end of reading).
A. Right.
Q. And that's to:
(Reading) I'm unable to discuss it further with you. Our Medical Information Group is best suited to talk with you. I'm happy to send your inquiry to them for follow-up (end of reading).
A. Precisely.
Q. And who would that go to in Medical Affairs, if such an inquiry came in?
A. A group of mainly Pharm.Ds on the front line of the phones, supervised by a physician, Eddie Darton, who reports to Herb Neuman.
And what actually happens is Dr. Jones calls in there and has a question; they field the question; they give a verbal response immediately on the phone; then they follow up with that physician with a letter reiterating what they talked about; the citations that Pharm.D is using as a basis for his answer and copies of the studies that were cited.
Q. Okay. So somewhere in Covidien document files in Medical Affairs will be notes, letters, et cetera, responding to some physicians who

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may have called, if they didn't get put off by the C.A.R.E.S. Alliance talk and actually wanted to discuss the merits of the article?
MR. DAVISON: Objection to form.
THE WITNESS: I'm going to really push back on this "put off" characterization. There's no putting off.
We are giving the physician options. Whatever that physician wants to do, we're on board with it. If the physician wants to get into the C.A.R.E.S. Alliance and adopt tools, we're good with it. We will help them. If the physician wants to talk to the Pharm.D people and Medical Information, we're good with it. If they want to do both, we're good would it. If they want to talk to Eddie Darton, we're good with it. If they want to talk to Herb Neuman, we're good with it. I guarantee they don't want to talk to me.
But this is the process that we've established. And this was just really reiterating -- there's nothing in here, this letter by Nancy Stauder, that isn't SOP, basic operating procedures within a pharmaceutical company. Because you can't have reps talking about things they are not trained on and not qualified to answer.

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BY MR. SAMSON:
Q. Okay. Back to the last real question I asked you.
Should there be -- if there were any physicians who wanted -- who were referred to Medical Affairs, there should be letters, there should be --
A. Okay.
Q. -- records, explanations of what was said to them about this article?
MR. DAVISON: Objection.
BY MR. SAMSON:
Q. And the issues in this article?
MR. DAVISON: Objection to form.
THE WITNESS: So it's better than that. There's -- there's a bank of called SRLs, standard response letters, that -- where we prespecified typical questions that are likely to be asked and preset responses, so the speed of response could be even better. But there's going to be questions -- and there's maybe 20 or 30 of those. But there could be questions that we didn't anticipate. Those -- those generate a fresh -- a fresh SRL. But that SRL has to go through clearance and review and oversight by physicians and signed off on ultimately by Herb.
So those are banked.

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BY MR. SAMSON:
Q. What is that bank called, if I wanted to --
A. Standard response letters.
Q. Okay. And are they kept, do you know, for any period of time?
A. I don't know.
Q. Okay.
A. Usually, I would think, pretty long.
MR. SAMSON: This one should be 9, but now 11.
(Exhibit No. 11 was marked.)
MR. SAMSON: Put 11 aside.
MS. GAFFNEY: Sorry about that.
THE WITNESS: Put 11 aside, okay.
MR. SAMSON: We have misnumbered it.
THE WITNESS: Okay.
MR. SAMSON: This will be 12.
THE WITNESS: I think it's the same number. 12 is the same as 11.
MR. SAMSON: Is it?
MS. GAFFNEY: Are we all set, then.
MR. SAMSON: Then we're okay.
Withdraw 12 for now. And I will put back 11.

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Q. All right. You have Exhibit 11 in front of you.
MR. DAVISON: Sorry, could I just make sure we have all MNK-T1, underslash, 0000941559. It's an email from Art Morelli to Rod Novak and others on April 26 --
THE WITNESS: No, not from me.
MR. DAVISON: Well, the very top one. I'm just trying --
THE WITNESS: Oh, the very top one.
MR. DAVISON: I'm just trying to make sure we have the same document. Thank you. I apologize.
MS. GAFFNEY: Thank you.
(Witness reviewing document.)
BY MR. SAMSON:
Q. Mr. Morelli, this is April 2011. So I think you should have been there yet?
A. I think so. Yes, my name is on there, so I was there, right.
Q. And you -- do you recall Remoxy, a competitive drug?
A. I do, yeah.
Q. And it was an ER generic oxycodone?
A. I think it was. I don't really remember. But it was -- its thing was its

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abuse-deterrent formulation.
Q. And, in fact, this -- another report in the literature coming out is about reaching an endpoint in Remoxy's study of whether its drug really was abuse deterrent in any form.
A. Okay.
Q. Is that what you get from the article?
A. I would have to really sit down and look at it. But it looks -- it looks like it is. Because they are comparing the ER formulation of Remoxy to the ER and immediate formulation of oxycodone in terms of various parameters, mainly drug liking.
So drug liking is a metric that you can compare products for their abuse potential.
Q. And for those of us who don't do pharmaceutical research, is drug liking intended to measure as a metric, "I like this not for its pain relief effect but as a high," so to speak?
MR. DAVISON: Objection to form.
THE WITNESS: I'm not a scientist. I don't -- I'm not into this kind of research. But that's what I've been told. I've heard that, yeah.
///

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BY MR. SAMSON:
Q. Okay. And so do you remember who the competitor was who made Remoxy?
A. Pain Therapeutics, maybe. I don't know. I think it is.
Q. Fair enough.
A. Yeah, it is.
Q. Okay.
A. It is. Remoxy is a registered trademark of Pain Therapeutics, Inc.
Q. Okay. And then if you will turn to -- I think it will be the -- since yours are copied on two sides, it will be -- page 1, 2 -- 3 at the bottom, and then page 4 at the top.
A. Okay.
Q. Do you see the "Study Results" is the boldfaced?
A. Study results. Oh, yes. Yes.
Q. Okay. So read me, without that odd gibberish at the start, symbols, the first finding endpoint analysis.
A. (Reading) Primary endpoint was drug liking. That was -- that was testing. As assessed by various pharmacodynamic parameters.

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Thirty-two subjects were included. Drug liking was significantly lower for Remoxy, 40 milligrams whole -- that means uncrushed -- compared with oxycodone immediate-release 40 milligrams or oxycodone immediate -- extended-release 40 or oxycodone immediate-release 40 (end of reading).
Q. And then what was the second finding?
A. (Reading) Drug liking was significantly lower for Remoxy chewed -- this is crushing it up -- compared with ER oxy and -- crushed and oxy IR 40 (end of reading).
Q. And I'm assuming the reason we don't see the IR 40 as being either crushed or chewed is that with an IR, it's going to be available in roughly the same amount of time, even without crushing?
A. It could be, yeah.
Q. I mean --
A. Makes sense.
Q. And then the next finding was time to peak drug liking, and that was also significantly delayed?

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A. Right.
Q. And that was, again, Remoxy chewed compared to oxycodone ER 40 milligrams crushed or oxycodone IR?
A. Right.
Q. And then what were the secondary endpoints?
A. Drug high, good effects, chewing duration, taste, texture assessments, and safety assessments. These endpoints generally demonstrated the same consistency of effects observed in the primary endpoints.
Q. And that's -- in terms of you reading that back when you were at Mallinckrodt, that's a potentially useful-for-safety difference with this new formulation; correct?
MR. DAVISON: Objection to form.
THE WITNESS: Potentially.
BY MR. SAMSON:
Q. Okay. And if its -- even at this stage, without saying it is absolutely proven, do you agree with me that that's good information for the entire prescribing population to know on the level that it's reported here?
MR. DAVISON: Objection to form.

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THE WITNESS: Yes.
BY MR. SAMSON:
Q. And did Mallinckrodt have an oxycodone extended release that had at this point any abuse-deterrent attempts at all?
MR. DAVISON: Objection to form.
THE WITNESS: No, not to my knowledge. But I wasn't in R&D. So I don't know what they had, really.
BY MR. SAMSON:
Q. But certainly not out in the sales market?
A. Oh, no, not out in the sales market.
Q. And so a 40 milligram oxycodone analog that has decreased drug liking and basically gives you a decreased high, even if you chew it or grind it up, could be a strong competitor for Mallinckrodt's existing hydrocodone ER?
MR. DAVISON: Objection to form.
THE WITNESS: As long as the efficacy was, you know, equivalent, yes. All other things being equal, abuse-deterrent formulations are one measure that is -- mitigates risk to patients.
BY MR. SAMSON:
Q. Okay. And who was Jamie Harrell?

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A. Jamie Harrell was basically the Chief Commercial Officer.
Q. Okay. So she's not --
A. It's a he. It's a he. But yeah.
Q. It's a he?
A. Yeah.
Q. He's not in Medical Affairs?
A. No.
Q. Okay. On the bottom of page 1 and going over on to the top of page 2 is Mr. Harrell's reaction. Can you read that aloud from me.
A. The whole part?
Q. From "I suggest."
A. (Reading) I suggest we create a Competitive Project team to do a deep dive on this product and build out a training program for the field to help them -- help position them in the marketplace. We need -- just thinking and typing out loud, we need to position them before they position us (end of reading).
Q. What did you take that "We need to position them before they position us" to mean when you read this stream?

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MR. DAVISON: Objection to form.
THE WITNESS: I had no -- I have no idea what he meant by that. But -- I don't know. I don't know what he was thinking. There's no way I could know that.
BY MR. SAMSON:
Q. It's a guy in commercial?
A. Right.
Q. A competitor's drug may have an advantage --
A. I don't --
Q. -- over Mallinckrodt's drug because --
A. Right.
Q. -- it has demonstrated decreased drug liking, and Mallinckrodt's competitive drug did not have any abuse-deterrent formula; right?
A. Right.
Q. What -- commercial, is that above marketing and sales, or part of it, or where?
A. It's composed of marketing and sales.
Q. So you're a veteran of the industry. When he writes, "We need to position them before they position us," after saying "We need to do a deep dive on this," what did you take from that?

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MR. DAVISON: Objection. Asked and answered.
THE WITNESS: I don't remember when it happened. If you're asking me what I would take -- meaning I would put now, in retrospect?
MR. SAMSON: Yes.
THE WITNESS: I would say that -- Remoxy wasn't on the market, so -- I don't know if it ever reached the market, actually, for whatever reason.
I would say this is a commercial guy asking for help, how to respond -- how to train salespeople to respond to questions, if they get them, on this new entry in the marketplace, which is what any pharmaceutical company would do, rather than let reps respond without being trained. He's asking for help. That's how I interpret it. And he's asking for help from Medical Affairs.
BY MR. SAMSON:
Q. How does that equate with "position them before they position us"?
MR. DAVISON: Objection to form.
THE WITNESS: I don't know what he meant by that. It's not something I would ever say.
BY MR. SAMSON:
Q. Okay. And then please read your

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response at the top of page 1.
A. (Reading) We are planning an abuse liability (formulation and PK aspects) consensus meeting with KOLs leading to a pub or two. And we will have details in a week or two (end of reading).
Q. Were those KOLs supported by Mallinckrodt?
A. Probably, yeah.
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. Okay. And why were you so confident that it might lead to a pub or two that might help what was worrying Harrell about the new study?
MR. DAVISON: Objection to form.
THE WITNESS: Because it would be in a way similar to what Pain Therapeutics has done here. They have published data on their product. We could publish data, if it exists, on our product. That's what it means.
BY MR. SAMSON:
Q. Abuse-deterrence data on generic oxy 40 extended release, that would be a long hunt, don't you think?

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MR. DAVISON: Objection to form.
THE WITNESS: I don't see this being anything to do with generics. This is to do with Exalgo. Jamie Harrell had nothing to do with generics.
BY MR. SAMSON:
Q. What did -- what was his position in commercial?
A. Branded -- branded products.
Q. Okay. All right.
A. Okay.
MR. SAMSON: That's that one.
The next one will be 12.
(Exhibit No. 12 was marked.)
MR. SAMSON: And this one, despite its thickness, Mr. Morelli, is really only the first page. And the rest I think are usage records or prescribing records.
THE WITNESS: Okay.
(Witness reviewing document.)
BY MR. SAMSON:
Q. And in -- Ms. Tonilee?
A. Tonilee is her first name. Masters is her second name.
Q. What was she -- was she in Medical

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Affairs?
A. Sales rep.
Q. Sales rep, okay.
And she apparently is setting you up for a meeting with a Dr. Gosy, who apparently has a fairly busy pain practice?
A. Right.
Q. (Reading) I want him to know the safety with REMS and C.A.R.E.S. program that he can receive for utilizing more Exalgo (end of reading).
Do you see that part?
A. Yes.
Q. And you were going to go have dinner with Dr. Gosy --
A. Right.
Q. -- to accomplish whatever you were going to accomplish with him?
MR. DAVISON: Objection to form.
THE WITNESS: To brief Dr. Gosy on the Exalgo REMS and the C.A.R.E.S. Alliance.
BY MR. SAMSON:
Q. Okay. Was that a common part of your job, to go meet individually with prescribers?

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A. No. It was very uncommon.
Q. Do you have any remembrance of Dr. Gosy?
A. So I travel to, I believe it was New Jersey for this meeting. Tonilee never showed up for the meeting. Stood me up. And I was left at the airport.
And when I spoke to her manager, who was Gavin McGowan, he told me Tonilee Masters resigned that day from the company. So the dinner never happened.
Q. Well, that --
A. I remember -- that's how I remember this occasion, because it was so remarkable, quite frankly.
Q. Okay. And although they may be interchangeable, if you will look, were you going to have dinner in Buffalo, New York --
A. Maybe that was it.
Q. So I couldn't tell -- you were going to New Jersey?
A. It was New York, yeah.
Q. So the meeting never went off. But was such a meeting common for you --
A. It was very rare. It was very rare.

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I remember doing another one.
MR. DAVISON: Let him finish his question.
BY MR. SAMSON:
Q. -- for you to go out to meet with individual physicians? Was that common or rare?
A. Rare.
Q. And I think you told me, while I was still asking the question, that you may have done it one other time, that you can recall?
A. Correct.
Q. And where was that other time?
A. Southern California.
Q. And who did you go to meet with directly as the prescriber in Southern California?
A. I don't remember.
Q. Do you remember a specialty?
A. Pain. It was pain. A pain specialist. He was very, very short. That's the only thing I remember.
Q. Okay. In your email response to Tonilee, you tell her:
(Reading) Thanks for the briefing. I prepared a summary of our most recent data related to Exalgo misuse, abuse, overdose and addiction (end of

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reading).
Correct?
A. Correct.
Q. "It will need to be communicated verbally." Why did it need to be communicated verbally?
A. Because that information is not in raw form, it is not cleared to be distributed to anybody we want. This is -- these are actual real-time reports into Medical Affairs of side effects and problems. So we just can't take a report, a company report, and hand it out. But we can communicate, in essence, what it is saying.
Q. Well, and, in fact, that's reporting evidence that's not on the label that's been approved by FDA; true?
MR. DAVISON: Objection to form.
THE WITNESS: I wouldn't say so, because these are side effects that the physician -- that are listed in the label as potential side effects. Or even if they are not, if they are idiosyncratic, you know, out of left field kind of side effects, the doctor has a right to know that this has been reported.
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BY MR. SAMSON:
Q. And I'm assuming that what you were eager to go show him were lack of side effects data?
MR. DAVISON: Objection to form.
THE WITNESS: I would -- was going to tell him what the data said.
BY MR. SAMSON:
Q. Okay. But you wouldn't have been anxious to do that if the reported side effect data that was coming in was larger than what was on the label; true?
MR. DAVISON: Objection to form.
THE WITNESS: I mean, it doesn't really matter to me. I'm going to report the data as the data is and let the data speak for itself.
BY MR. SAMSON:
Q. Say if --
A. The only thing he needs to do is the denominator. This is a numerator. He needs to know what the denominator is.
Q. And why couldn't that be given to him in writing?
A. It could have been. It could have been sent in an email, maybe. But it's just more personable to do it face to face. He may have 17

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questions on what I tell him, so he may ask me. And if he has further questions, maybe Eddie Darton has to go see him.
Q. And I didn't draft this email. You did.
A. Right.
Q. "It will need to be communicated verbally."
A. Right. I'm not going to hand him the raw data from our -- from our safety database.
Q. But you're going to tell him that same raw data?
A. Right.
MR. DAVISON: Objection.
BY MR. SAMSON:
Q. Okay. You weren't trying to get around one of those things, like sales personnel can't say anything other than what's on the label?
A. I didn't want --
MR. DAVISON: Objection.
THE WITNESS: I didn't want to put the sales rep in a position to do something that they are not comfortable doing nor are they authorized to do. That's why I was taking the heat off her, and I was speaking with the physician.

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BY MR. SAMSON:
Q. So you never met with Dr. Gosy?
A. I did not.
Q. So you left neither a verbal trail or a written trail because the meeting never came off; true?
MR. DAVISON: Objection.
THE WITNESS: It's not a question of a trail. The meeting never came off.
BY MR. SAMSON:
Q. Why did you need to see his prescribing data to accomplish that mission?
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. The rest of the many pages of the email.
A. I don't even know what this -- oh, I see.
Q. It's the various opioid medications and how much he's used --
A. I didn't need to see it. I didn't need to see it. She sent it to me.
Q. Did you --
A. It wouldn't make any difference to me, quite frankly, what this data is. His question

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is about Exalgo.
Q. If you look on the page that includes Exalgo. Do you see it? It's right at the top.
A. Oh, yeah, I see it.
Q. You're now on the page.
A. Right.
Q. It doesn't appear that he is using much Exalgo.
A. I can't tell from --
MR. DAVISON: Objection.
THE WITNESS: -- this. I don't know what these numbers means.
BY MR. SAMSON:
Q. If you look down at "Generic for immediate release," immediately below.
A. It's probably the case.
Q. It's probably the case that he wasn't using it --
A. Right.
Q. -- which is in line with the original email?
A. Right. Right.
So here's how I interpret this. Here's a physician who's a pain specialist. He treats a lot of patients. He writes a lot of prescriptions for

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opioids, high-powered opioids. He's concerned about the safety of the drugs that he's prescribing.
I'm there to provide information to him related to the safety of the new drug on the block, the one that he doesn't have much experience with, in terms of what we are seeing and what's being reported for our drug.
And the programs that we have in place, one for Exalgo specifically, the REMS, and, two, for all the other opioids he's prescribing, Vicodin and Avinza, and all these others, that he could potentially adopt in his practice and make his whole practice safer.
And he's got all these PAs and NPs working for him. Maybe set up a lecture, a lunch and learn for them so that they can be exposed to these tools and these programs, because they are going to be the ones, more than likely, that are going to actually implement it.
Q. Did he ever become an Exalgo big prescriber?
A. I have no idea.
Q. Just --
A. I never heard of him again.
MR. DAVISON: We have been going another

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hour and fifteen. Can we take a break?
MR. SAMSON: Yes.
MR. DAVISON: Or is this short?
MR. SAMSON: Well, I think this one is pretty short.
MR. DAVISON: Okay.
MR. SAMSON: This will be 13.
(Exhibit No. 13 was marked.)
(Witness reviewing document.)
BY MR. SAMSON:
Q. This takes up a program that you had mentioned earlier in the day about, was it an Exalgo-specific program when you launched it, the "Expert on the Call"?
A. Yes, this is an Exalgo-specific program.
Q. Okay. And Ms. Blasser has seen the PowerPoint for "Expert on the Call"?
A. Right.
Q. I take it that would have been a PowerPoint Medical Affairs had put together?
A. In a training program, yeah.
Q. Okay. And, basically, as I -- there's a couple more of these we will deal with.
It sounds like experts were recruited by

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Medical Affairs to be a participant in "Expert on the Call," where they would get calls from outlying physicians who had questions about Exalgo and could talk to them; is that --
A. That's exactly what it was.
Q. Okay. Were those experts on the call paid?
A. Yes.
Q. How much?
A. I don't remember.
Q. Was it for a call or only a successful call that resulted in an Exalgo script being written?
A. A call.
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. And do you recall, was it a hundred bucks for a call, or so much per minute, or any other figure?
MR. DAVISON: Objection to form.
THE WITNESS: I don't recall how exactly we calculated the honorarium, but there was an honorarium.
BY MR. SAMSON:
Q. Okay. And am I safe in assuming that

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the experts were prescribing themselves Exalgo?
A. I would say, for the most part, yes. For obvious reasons, yeah.
Q. And what are the obvious reasons to you? Because they may be different than mine. But they may be the same.
A. A physician gains a lot of knowledge when they actually use a product. They have actual experience. And that it could be important to another physician. When physicians share information doctor to doctor without a pharmaceutical company interceding, they could be more frank or more, you know, clear, clearly communicate with each other.
Q. Well, and they are much more likely to communicate favorably about Exalgo if they are using it, true, just in the realm of human nature?
MR. DAVISON: Objection to form.
THE WITNESS: No. I would say they would be very honest. The physicians I work with would be very honest.
BY MR. SAMSON:
Q. How many expert on the calls for Exalgo were not prescribing Exalgo?
A. I don't remember that.
Q. Do you know --

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A. Most of them -- I would say most of them were prescribing Exalgo.
Q. The --
A. In fact, we -- we were -- we hoped that they were so that they would have hands-on experience, yeah.
Q. What -- why would they be in a program for a drug that they didn't use?
A. Except to make money, I can't think of another reason. So that's why we wanted them to be prescribers of Exalgo.
Q. Okay.
A. But we didn't -- we really didn't enforce that, to make that an absolute, because then it could be said that we were strong arming them to become a prescriber by -- by providing an inducement. So it really wasn't that clear-cut.
Q. And Ms. Blasser greets you and says:
(Reading) I just saw the PowerPoint for "Expert on the Call." Program looks awesome. As we discussed at the advanced training meeting (end of reading) --
Which I'm assuming is probably where she saw the program?

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A. Probably, yeah.
Q. (Reading) -- I have a candidate for this, Dr. Lance Yarus. He has a lot of experience writing Exalgo, is a current KOL speaker with good reviews, and is a well-respected orthopedic surgeon/pain management physician in Pennsylvania (end of reading).
Did I read that correctly?
A. Uh-huh.
Q. And you write back:
(Reading) Nice to hear from you. Dr. Yarus could be a good fit for the program if you believe he would benefit from a consultation with a pain specialist on the specifics of rotating patients to Exalgo (end of reading).
So did you believe that she was putting Dr. Yarus forward as a caller into an "Expert on the Call"?
A. Yes. A participant.
Q. Okay. And were callers in on the EOC program given an honorarium or any --
A. No. No.

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Q. Just got the information?
A. Right.
Q. For their benefit?
A. Right.
Q. And do you remember whether or not Dr. Yarus took advantage of that opportunity?
A. Of course I don't remember. But I'm thinking, from the communication on top, it looks like he didn't. But I can't be sure.
Q. And what is it about Ms. Blasser saying, "Please let me know your thoughts" --
A. And then she said, "Never mind. He didn't understand my question."
I don't know who is "he." I don't know who is "he" that she is referring to. It may have been me, that I didn't understand her question.
But I don't recall this going any further or whether it happened or didn't happen. It could have happened.
MR. SAMSON: All right. Let's take our break.
MR. DAVISON: Thank you.
THE VIDEOGRAPHER: We are going off the record. The time is 3:16 p.m.
(Recess taken.)

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THE VIDEOGRAPHER: We are back on the record. The time is 3:28 p m.
THE REPORTER: Next in order is 14.
MR. SAMSON: 14.
(Exhibit No. 14 was marked.)
(Witness reviewing document.)
BY MR. SAMSON:
Q. Mr. Morelli, this one comes from August of 2011 and is, again, on the EOC. This time an update.
A. Right.
Q. And that's the EOC program for Exalgo; true?
A. True.
Q. And the first message from you on page 2 --
A. Yes.
Q. -- sent August 20th, appears to be an update showing two spreadsheets for -- are these the marketing and sales force, or who is this original report aimed at?
MR. DAVISON: Objection to form.
THE WITNESS: So the report was compiled by Leah La Roux, as you see there, who is a Pharm.D in our Medical Division of Medical Affairs. And what

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Dr. -- Dr. Newman and I kind of agreed to, a bit on the sly here, is we had Leah and other -- and other health-care professionals secretly, secretly listen in on these calls without divulging their presence, to ensure that the information being communicated was appropriate, not off the label of the product, unless it was, you know, not related to the label. Like one doctor asked another doctor a doctor question, not a product question, you know, which is always possible.
But in terms of the relevant product information, we put in a little quality control here to make sure that this wasn't going off the rails. And you can see from Leah's -- Leah's feedback that so far it's looking good. That was the first email that I wrote there.
BY MR. SAMSON:
Q. Okay. And, in fact, what Ms. La Roux -- what you quoted her as saying is, quote:
(Reading) The majority of calls have been extremely successful in educating HCPs on the intricacies of Exalgo that will lead to increased prescriber confidence while promoting the safe use of our product (end of reading).

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True?
A. True.
Q. And so promoting safe use of our product is an admirable goal; true?
A. I think it's extremely admirable.
Q. And the other one increased prescriber confidence while in Exalgo is a good effect on corporate sales and, thus, success or failure of Exalgo; true?
MR. DAVISON: Objection to form.
THE WITNESS: Correct.
BY MR. SAMSON:
Q. And then the next middle part was a success story from Denver -- or from the Western Regional Sales Director, from a Sales Specialist, directing his number two opioid prescriber in the territory and his number four, who happened to work in the same office, to the "Expert on Call" program. And after that talk, the doctor said he was ready to prescribe Exalgo; true?
MR. DAVISON: Objection.
THE WITNESS: It seems so here, yes.
BY MR. SAMSON:
Q. And you write back:
(Reading) This is a phenomenal story.

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Thank you for sending it (end of reading).
True?
A. I did, yes.
Q. Okay. And is that because the two goals we talked about, in Ms. La Roux's report to you, you could see being met? Here's someone getting the use in intricacies of Exalgo explained to them, and then turning around and writing them?
MR. DAVISON: Objection to form.
THE WITNESS: They're -- they're -- they're different, but they are related. I'm not sure what you're asking me, though.
BY MR. SAMSON:
Q. Well, tell me why they are different but related.
MR. DAVISON: Objection to form.
THE WITNESS: So Leah -- the purpose of Leah's communication here is to basically do some quality control on the physicians, how they were responding to the call-in doctors.
Whereas, Connie's forwarding this basically commenting on Dr. Arnoff, that Dr. Arnoff was effective -- effective in familiarizing this doctor with Exalgo, who was previously unfamiliar. It

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may -- it was two doctors, actually. And Dr. Arnoff was at that time, and still, a recognized, you know, leader in pain management, a respected individual. So that's -- that's how that worked, you know.
BY MR. SAMSON:
Q. But the outcome, that was part of you saying it was a phenomenal story, was that the number two prescriber and his nurse practitioner, who was the number four prescriber in this region, who hadn't been prescribing Exalgo, were now prescribing it?
A. Yeah.
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. And you assume, because I think that you never got to question those two physicians, that the explanation given of the Exalgo's intricacies had led them to open the door to wanting to prescribe it?
MR. DAVISON: Objection to form.
THE WITNESS: And -- of course. Of course. But how to -- how to rotate patients on to Exalgo.
BY MR. SAMSON:
Q. Okay. That -- that was a specific danger that the Exalgo intricacies presented; true?
MR. DAVISON: Objection to form.
THE WITNESS: It was -- it was a high risk

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area, but it was also an opportunity for patients that weren't getting pain relief on their existing analgesic.
So, remember, Exalgo is second line. So only patients who are already -- have opioid current -- current opioid experience are candidates for Exalgo. So by definition, then, anybody that goes on to Exalgo has to come off their current opioid. That process is opioid rotation.
So how do you do that? How you do that is pretty -- pretty delicate. The patient could be either exposed to pain or could be exposed to receiving too much drug, if it's not done properly, because of a principle of incomplete cross tolerance.
BY MR. SAMSON:
Q. And Exalgo had a challenging, unset time to add to that difficulty?
A. Slow.
Q. Yes.
A. Right.
Q. I mean, it -- it wasn't -- if I'm taking IR molecule 1, and my doctor changes me to IR molecule 2, I might still have a reaction to 2. But in terms of getting 1 out of my system and 2 in without causing the combination that may be dangerous

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to me, there's not much trouble; correct?
MR. DAVISON: Objection to form.
THE WITNESS: There's not much?
BY MR. SAMSON:
Q. Trouble compared to an Exalgo slow onset --
A. Oh, I see what you mean.
Q. -- effect?
A. Yeah, it's more complicated because you have one drug that's fast onset, fast offset. And you have the second drug, the one you're going to, is slow onset.
So that's why, one of the reasons why we have this program. Because this program -- that -- that intricacy, right. So here's -- that intricacy requires a lot of expertise.
MR. SAMSON: 16. It was 14.
THE REPORTER: I'm up to 15.
MR. SAMSON: Oh, 15. You're right.
(Exhibit No. 15 was marked.)
(Witness reviewing document.)
BY MR. SAMSON:
Q. This starts out, Exhibit 15, with an email from Jeff Patrick. And what division was he in?

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A. Medical Affairs.
Q. And did he answer to you directly or to someone else?
A. He answered to Herb.
Q. And he's attached an article asking whether anybody on your team had reviewed it; correct?
A. Correct.
Q. And the article from its abstract is hydromorphone being a molecule of particular interest, given its subjective similarities to heroin and tendency to be misused by -- misused by illicit opioid users.
A. Right.
Q. Exalgo was hydromorphone?
A. It was. It is.
Q. Extended release because of its capsule?
A. Correct.
Q. So I'm assuming, with Exalgo being new to the market, an article that compared it to heroin in misuse would not be welcomed at Mallinckrodt?
MR. DAVISON: Objection to form.
THE WITNESS: It would be another piece of

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data that we have to take into account based on what we're doing, yeah.
BY MR. SAMSON:
Q. But in truth, in terms of promotion and sales of Exalgo to prescribing physicians, you would have issued that the article came out differently than what its authors concluded; true?
MR. DAVISON: Objection to form.
THE WITNESS: No. No. I would hope that the article would come out and the data would speak for itself --
MR. SAMSON: Okay.
THE WITNESS: -- as it has here.
BY MR. SAMSON:
Q. And what is the data speaking for itself?
A. It's just --
MR. DAVISON: Objection to form.
THE WITNESS: It's just basically saying that something we already knew anyway. Hydromorphone is a potent opioid. It produces, you know, a high degree of liking amongst addicts or pre-addicts. And that's just the facts.
So -- and that's my response, was we can't wait around for all data that may come out years in

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the future. We have to continue with the pressure on risk mitigation, because we don't know what's going to happen. So we have to plan for the worst and keep pushing the rock up the hill in terms of providing ways to use this product safer.
BY MR. SAMSON:
Q. And in the conclusions of the abstract, it says:
(Reading) Additional investigations into hydromorphone are warranted, particularly given previous findings regarding the prevalence of non-medical use of this document and its similarities to heroin (end of reading).
And you took that, as you just said, to mean that Exalgo seems different than a hydromorphone immediate-release formulation in these aspects; true?
MR. DAVISON: Objection to form.
THE WITNESS: It's different in those aspects.
BY MR. SAMSON:
Q. And where -- what data did you have to document that?
A. There was -- there was no Exalgo in

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this study. This was a hydromorphone study.
Q. Okay.
A. So -- but the active ingredient of Exalgo is hydromorphone. So what I was saying here is, regardless of this data and regardless of the differences of Exalgo, we have to stay on plan to communicate ways to use this drug safer. It has risks. It has serious risks that can be mitigated, at least partially mitigated, by the use of accepted tools and programs designed to mitigate that risk and to protect patients from harm.
Q. Okay. But your determination that Exalgo is different than hydromorphone IR formulations in the aspects of its appeal to its similarity to heroin and its appeal to misuse by drug abusers, there was no study that proved that; true?
MR. DAVISON: Objection to form.
THE WITNESS: No. And I didn't say there was. I said Exalgo seems different.
MR. SAMSON: Okay.
THE WITNESS: From what I know about its kinetics versus what the study drug was here, which was immediate-release hydromorphone.
No one is denying the risk of Exalgo. Nobody knows it better than me, and no one is

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championing doing something about it more than me and my team.
BY MR. SAMSON:
Q. But saying it's different from the IR formulations in the study is simply a hope; true?
MR. DAVISON: Objection to form.
THE WITNESS: I don't think so. I think it's different. Exalgo is not the same as immediate-release hydromorphone. That's just a fact. It doesn't mean it has no risk. It has plenty of risks.
I designed a whole program to mitigate those risks. We don't -- we're not dealing -- we're not selling IR hydromorphone. We're selling Exalgo. And my responsibility is to make Exalgo as safe as humanly possible.
BY MR. SAMSON:
Q. And in the pharmacokinetics, the difference between Exalgo and IR hydromorphone is a sharp peak in IR hydromorphone and a similar rise, but then more of a plateau for Exalgo; true?
MR. DAVISON: Objection.
THE WITNESS: Slower. A much slower rise. A much slower onset of effect.
///

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BY MR. SAMSON:
Q. Okay. And your suspicion is that if tested for drug liking, that would show a difference between IR hydromorphone?
A. It could. It could not. I'm just saying it's different. I'm not saying it's superior. I'm not saying it's safer. I'm not saying it's less abusible. I'm just saying it's different.
When we communicate information on Exalgo, we're not communicating information on IR hydromorphone. That's not our product.
Q. And so "not according to wait for definitive scientific proof that our, bracket, Exalgo, end bracket, measures are effective, bracket, in making a different outcome than IR hydromorphone," was not what you were talking about? You were talking about, we have to keep on our program of trying to decrease misuse of Exalgo?
A. Precisely.
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. Let me ask you to turn back to Exhibit 6.
A. There it is again.
Q. It will be the thickest one in your

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stack.
A. Okay. Got it.
Q. And this is the sales force training REMS and safe use.
A. Okay.
Q. And I will ask you to turn to the first actual slide instead of just the title slide.
A. Okay.
Q. The one on your left.
A. Got it.
Q. And this is a -- an address from Dr. Lynn Webster addressed to the sales force.
A. Right. It was a video.
Q. Okay.
A. A video.
Q. We talked about Dr. Webster earlier. You remembered his name?
A. Yes.
Q. And that he worked at Lifetree Clinical Research and Pain Clinic?
A. Right.
Q. And why did you think he was a -- the right person to address the sales force in terms of -- I'm assuming this is -- since it's REMS and safe use, it's Exalgo related?

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A. Yes.
Q. Okay. So why Dr. Webster?
A. Because of his experience, his knowledge, his rational approach to things, his balanced approach, his concern for overall patient care and well being, and he's very articulate.
Q. Was he paid either through your budget or some other budget to do the video that was shown to this sales force?
A. He was.
Q. And which budget?
A. Ours. Medical Affairs.
Q. Do you recall how much?
A. No, I don't.
Q. Okay. At the time you left Mallinckrodt, I'm assuming that that -- a video of that presentation would have been available -- was still there?
A. I assume.
MR. DAVISON: Objection to form.
THE WITNESS: Don't know, though. Yeah, we used it multiple times, obviously.
BY MR. SAMSON:
Q. And -- I think you told me earlier that Dr. Webster was also active in the American

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Academy of Pain Management?
A. He was.
Q. Was on the board, or whatever their directing body was, at one point or another?
A. He was.
MR. DAVISON: Objection to form.
THE WITNESS: He also published a book, "Avoiding Opioid Abuse While Managing Pain, A Guide for Practitioners." So he clearly thought about the dichotomy, the risks, and the benefits. We wanted someone who was going to give, you know, a message that's appropriate for sales representatives to hear.
BY MR. SAMSON:
Q. Okay. And was he, at any time while you were at Mallinckrodt, a Covidien KOL, a key opinion leader?
A. He was a KOL for the safe use program and the REMS program, not for commercial -- interaction with the commercial organization.
Q. In that place as a KOL for REMS and safe use, he would have been under your budget in Medical Affairs?
A. Yes.
Q. And were there specific Exalgo budget outlines in your Medical Affairs?

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A. That I don't remember.
Q. Did he or Lifetree get any grants from Covidien that you know?
A. He did one study for us with Exalgo post approval.
Q. And what was that study?
A. So Dr. Webster submitted a study proposal for funding, which we reviewed and decided to fund, because we thought it was very crucial for the safe use of the product.
Q. And what was the subject of the said study?
A. The subject of the study was, what is better for patients; to dose Exalgo once a day in the morning, or to dose Exalgo once a day in the evening? Whether there's any difference in terms of adverse events based on those two dosage schedules with the same dose. And also evaluating pain on awakening.
So for patients with chronic pain, pain on awakening, is a very poor measure. Because if they have pain on awakening, it's difficult for them to start their day and to have a productive day, in terms of their activities of daily living.
So pain on awakening versus a nighttime dose or a morning dose. So he -- he completed the study,

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and he published the study.
Q. And what, if you recall, was the general outcome of the study?
A. The general outcome of the study was pain on awakening was exactly the same, no statistical difference. However, the side effects were different.
Q. And what were the --
A. There was more -- more indications of respiratory depression dosed in the evening versus dosed in the morning.
Q. And did that research paper and finding lead to any label changes, like asking the FDA to let us say to dose it in the morning?
A. It did not. Because it wasn't really powered.
Q. Not enough participants?
A. Yes. It would have been -- a much bigger study was needed. But we incorporated that into our educational materials.
Q. Had -- at the time that you left Mallinckrodt, had you personally met Dr. Webster?
A. Oh, I've met Dr. Webster many times.
Q. Okay. And did you have a high opinion of him?

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A. Extremely high.
Q. He developed a five-question survey that he called, "The Opioid Risk Tool"?
A. The ORT, O-R-T.
Q. And you are a supporter of that tool?
A. It was one of the tools in the C.A.R.E.S. Alliance.
Q. And he asserted that it would, quote, predict accurately which individuals may develop aberrant behaviors when prescribed opioids for chronic pain; true?
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. As you recall it?
A. As I recall it.
Q. And was the book -- or one of the books that he published called, "The Painful Truth: What Chronic Pain is Really Like, and Why it Matters To Each of Us in Avoiding Opioid Abuse While Managing Pain"?
A. I don't know the book per se. But it sounds like something he would write.
Q. Have you ever read his book? Did you read it back at the time?
A. Not at the time, no.

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Q. And not since?
A. No.
Q. Okay. Were you aware Dr. Webster and the Lifetree Clinic were investigated by the DEA for over-prescribing opioids?
A. I was aware of that.
MR. DAVISON: Objection.
BY MR. SAMSON:
Q. And apparently it was -- they had 20 patients die from overdoses that led to the --
A. That was the contention.
MR. DAVISON: Objection to form.
THE WITNESS: That was the contention, as I remember. I don't remember the exact number. But there was a contention or an allegation, I guess is the right word of that.
BY MR. SAMSON:
Q. And do you recall that the DEA reported that he was prescribing a staggering number of opioid pills to patients under his care?
MR. DAVISON: Objection to form.
THE WITNESS: I don't recall that. But that's what those things usually are.
BY MR. SAMSON:
Q. That's where what?

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A. That's what the things are usually about. But I don't -- I don't recall.
Q. Investigations?
A. Yes. I don't know what the actual investigation was about.
Q. In fact, there was someone, a Lifetree patient, who overdosed in 2007 who was taking as many as 32 pain pills a day in the year before she died; do you recall that?
MR. DAVISON: Objection to form.
THE WITNESS: I do not know anything about that.
BY MR. SAMSON:
Q. Would -- there's another patient who sought treatment for pain at Lifetree after a serious car accident and multiple spine surgeries, quickly became addicted to opioids, and was prescribed increasing quantities of pills. At the time of her death, she was on seven different medications, totaling approximately 600 pills a month. Did you hear of that?
MR. DAVISON: Objection to form.
THE WITNESS: No.
BY MR. SAMSON:
Q. Another one who sought treatment from

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Lifetree for chronic low back pain and headaches died at age 42 after Lifetree clinicians increased her prescriptions to 14 different drugs, including multiple opioids, for a total of 1,158 pills a month. Were you aware of that?
A. No.
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. If those three stories were consistent with the practices at Lifetree, would that fit within Art Morelli's definition of a pill mill?
MR. DAVISON: Objection to form.
THE WITNESS: I hesitate to say "yes" or "no," because pill mills are a very, very unique kind of thing versus just garden variety, you know, high-dose prescribing or over-prescribing, because of the economic angle and the pharmacy combined with the office angle.
So I wouldn't necessarily put that in a pill mill box, no.
BY MR. SAMSON:
Q. Since some of these things were in 2007 and 2008, at least as reported, Dr. Webster would have had them on his copy book at the time that you were introducing him to your sales staff at

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Covidien; true?
MR. DAVISON: Objection to form.
THE WITNESS: Chronologically, yes.
BY MR. SAMSON:
Q. Did you know about any DEA investigation or patient deaths at the time when you were presenting him to the sales staff?
A. I did not.
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. I take it, based on Art Morelli's approach to truth and evidentiary-based results, had you heard those things, you would have had them investigated and found out the truth of them?
A. Absolutely.
MR. DAVISON: Objection.
BY MR. SAMSON:
Q. And if, in fact, patients at Dr. Webster's clinic were getting as many as 32 pain pills a day, would you be inviting him into Mallinckrodt?
MR. DAVISON: Objection.
THE WITNESS: I can't judge. But that's a lot of pills. So, you know, it would be a red flag.
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BY MR. SAMSON:
Q. 600 pills a month, a real red flag?
A. It --
MR. DAVISON: Objection.
THE WITNESS: It seems like a lot. I found out about these allegations from a friend, who is also a physician, way, way after that. Way after I was gone.
BY MR. SAMSON:
Q. Did you -- did you happen to call anyone who you knew at Covidien, who was still there, and say, my God, look at what -- I just learned this stuff about Dr. Webster; is he still on staff?
A. No, I did not.
MR. DAVISON: Objection.
MR. SAMSON: Let me withdraw it because "staff" was poorly used.
Q. Was he still in the Covidien orbit of speakers?
A. I haven't spoken --
MR. DAVISON: Objection.
THE WITNESS: -- to Dr. Webster since the day I left Covidien.
BY MR. SAMSON:
Q. Did you speak with anyone at Covidien

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to pass on the information you had heard? Because I'm assuming what you heard did not qualify him, in your eyes, as remaining a spokesperson for an organization you were involved with?
MR. DAVISON: Objection.
THE WITNESS: I did not. I did not.
MR. SAMSON: 17?
THE REPORTER: I'm at 16.
MR. SAMSON: Oh, that's right. We're back to 1.
(Exhibit No. 16 was marked.)
BY MR. SAMSON:
Q. Mr. Morelli, this is a February 2011 --
A. Okay.
Q. -- about a REMS KAB survey, email string.
(Witness reviewing document.)
A. Ah, okay. Okay. I see this. I see this. Okay.
Q. Are you finished reading?
A. I am.
Q. Okay. Is this an episode that you recall independently, now that you've read this email string?

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A. I do.
Q. Okay. And if you'll turn to the second page, the back of the first page for you, a Tammy Spicer writes to Shawna Hawkins -- Hankins about an experience she's just had with a nurse practitioner in a pain management office.
A. Right.
Q. Who was Shawna Hankins? In Medical Affairs or outside?
A. District -- District Sales Manager in the -- kind of the Arizona area.
Q. And if you'll start reading for me in the first paragraph after "Hi, Shawna." And you may have already seen this, that sentence. The sentence that starts with, "Ironically."
A. She was -- she's saying she was blindsided.
Q. "With it."
Go ahead and just read it, please, for the record.
A. (Reading) Ironically I was blindsided with it at no other than Sandy Gallo's office, wherein I had just gotten approval to mention Exalgo in her office (end of reading).

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That part I don't understand.
Q. Well, as I read it --
A. I don't understand what was going on here.
Q. Okay. Well, do you remember Sandy Gallo as perhaps a high prescriber of --
A. I don't remember.
Q. -- or a big cheese in pain management?
A. I don't remember the name Sandy Gallo, no.
Q. So I'm assuming that what Ms. Spicer is talking about, is that physicians may or may not be interested in hearing about a new medication?
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. Well, when I read, "I just got an approval to mention Exalgo in her office," I'm assuming Sandy Gallo has the power of which drug reps she wants to let into her office and which drugs they get to talk about. Does that --
A. It could be.
MR. DAVISON: Objection to form.
THE WITNESS: It could be. I don't know.
MR. SAMSON: Okay.

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THE WITNESS: Yeah.
BY MR. SAMSON:
Q. And then read on from, "To highlight the document."
A. "You can't give me a pen, and now you're paying me for prescriptions." Which, of course, is not the case.
Q. Hold on. You skipped --
A. Oh, I missed something.
Q. You read through, "Mention Exalgo in her office," in the first paragraph. Start that next sentence.
A. (Reading) To highlight the document, it's an offer to pain docs for $100 per Rx up to ten, if they write Exalgo and complete a survey. It says it's cosponsored by Covidien, though I saw no logos. Her objections were the following (end of reading).
Q. And then, 1?
A. (Reading) You can't even give me a pen, and now you're paying me for prescriptions? You told me the FDA and its concerns over REMS, why -- why -- why you could discuss Exalgo during lunch. How exactly is this going to affect your REMS -- which I don't understand -- I have seen a lot of cases where the surveys are paid but never scripts. This is going to hurt the pain community. I don't know who else should see this, but we, as sales reps, definitely need some kind of official position on this. My apologies for having no idea how to handle this one (end of reading).

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Q. Okay. And then somehow Shawna responds -- it says, "Shawna responds." Oh, there it is. Or moves it up to you and Mr. Wickline?
A. Yes.
Q. Okay. And says -- or to Mr. Wesler, I guess is the "Mike" in --
A. He's the Mike, yeah.
Q. And wants to know where we landed on this one with sending out a heads-up to the customer facing teams?
A. Yes. In other words, inform them of what's taking place.
Q. Okay. And then Ms. Kissinger chimes in and says that Lori Macklin saw this in her territory last week too.
Do you remember a Lori Macklin?
A. No, I don't. I remember Kissinger but not Lori Macklin.
Q. Okay. And then Mr. Wickline writes to you.
A. Right.
Q. To say that it would appear that the REMS survey is causing some concern among some of our customers and catching the reps off guard.
A. Right.
Q. Well, first of all, was it true that there was a hundred dollar per prescription of Exalgo, up to ten, that a provider wrote as long as they agreed to fill out a survey?
A. No.
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. Okay. What was the program for -- I'm assuming this is a KAB survey?
A. This is a KAB survey --
Q. Which --
A. -- required by the FDA.
Q. Which stands for?
A. Knowledge, attitude, and belief.

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Q. Okay. And so how did this message -- you're saying no one was offered a hundred dollars to fill out that survey?
A. Oh, no. They were offered a hundred dollars to fill out the survey. Quite clearly.
Q. Okay. And were they required to have written a prescription before they got the survey?
A. That I don't --
Q. A prescription for Exalgo?
A. That I don't remember. But I think they were. Because this was a REMS -- this was a survey about KAB related to the product required under the auspices of our REMS program.
And I -- my organization -- my team, Jenny and my team, designed and implemented this. We purposely did not inform the sales force -- maybe in retrospect that was a mistake -- because what we didn't want is the sales force running into these doctors and using this as a way to talk to the doctor about stuff they don't need to be talking to the doctor about.
This was needed to be a blind, straight survey, the results of which -- the protocol for this was approved by the FDA. The sample size was approved by the FDA. And the FDA wants the results

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sent to them to review.
Q. And did you tell the FDA that you were going to pay people to fill out the survey?
A. Yes. And they approved the amount of the payment under their guidelines.
Q. And was it -- where did the up to ten prescriptions per hundred dollars come from?
A. I don't know. Maybe what I'm thinking, is maybe the guideline was the physician should at least have ten patients or written ten prescriptions on Exalgo to have a sufficient experiential base to answer the survey properly. That's the only thing I can think of.
Q. And then they got a hundred bucks, the physician, or did they get a larger amount?
A. No, they got a hundred.
MR. DAVISON: Objection.
BY MR. SAMSON:
Q. And then later, up above, your response is that:
(Reading) You agree with what you just told me, the details of the REMS assessment and the need for the KAB survey at the manager's meeting (end of reading).

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And I'm assuming that's you or somebody from Medical Affairs --
A. Right.
Q. -- telling district managers, regional managers --
A. Both.
Q. -- why it was, and they could then pass that on to their people?
A. Right.
Q. Their respective people; correct?
A. It would have been better, in retrospect, to announce that the study was being conducted, but don't give the names of the physicians, but just a blanket 150 physicians across the country are going to fill out a survey. You don't need to know who, what, when, why, or where, because we don't want your sticky fingers inside this survey.
Q. Then, number two, which you said:
(Reading) Agree, would be to discuss with sales, marketing and Medical Affairs, advisability of a field communication on the subject. We can prepare it (end of reading).
A. Yes.

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Q. She agreed with that?
A. Jamie. Jamie is a guy. But, yeah, he agreed with it.
Q. Okay. And then you thought address it during breakouts at the NSM via sales management at the PPS Team.
A. Right.
Q. Can you --
A. National Sales Meeting, NSM. PPS, Patient Product Safety team.
So we had our people fan out to the meetings, wherever they were held, to conduct this breakout.
Q. And basically you told them before the next steps, that you had met your FDA and -- for surveys of 150?
A. Yes. So we're not recruiting anymore physicians. Yeah.
Q. But then you were going to have another survey in a few months, in which the survey respondents need to be different?
A. Right. So the requirement of the agency is you do two surveys with "X" amount of time in between. But not the same doctors. So they compare the results in this to the results in this,

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two different surveys.
Q. And no patient input in the survey process? I mean, patient surveys?
A. That I don't recall. There may have been a thing in there where the physician had to ask the patient a question. I don't recall. I'm pretty sure it was just the doctor.
Q. And then you see the black box, which is --
A. Yeah.
Q. -- has been redacted. As we saw earlier, your social security number, or things like that, are often redacted.
This one, William, puzzles me. Do you recall --
MR. DAVISON: I mean, I don't recall --
MR. SAMSON: -- by any chance, what --
MR. DAVISON: -- off the top of my head. You can take a look at our redaction logs that we have produced on these items.
MR. SAMSON: Okay.
Q. I mean, given that your response and answers about the survey are not -- and unless you went to a lawyer in-house, wouldn't be privileged, do you have any idea what else might have been on here?

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MR. DAVISON: Objection. I mean, you're asking him to talk about something that's clearly been redacted. I think that's incredibly inappropriate, to be honest, Mark.
MR. SAMSON: Okay.
MR. DAVISON: I'm going to instruct the witness not to answer.
MR. SAMSON: All right. Let's go to No. 17.
(Exhibit No. 17 was marked.)
THE WITNESS: I'm going to need a bio break after this one.
MR. SAMSON: You got it.
Do we have the attachment marked separately?
Let's reschedule your bio break.
THE WITNESS: Okay.
THE VIDEOGRAPHER: We are going off the record. The time is 4:19 p m.
(Recess taken.)
THE VIDEOGRAPHER: We are back on the record. The time is 4:29 p m.
BY MR. SAMSON:
Q. Mr. Morelli, you now have what's been marked as Exhibit 17 in front of you, which is a single-page email and then attachments, which are the FDA comments on the REMS documents. And I'm assuming

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they are the REMS for Exalgo?
A. Yes. It says here this is Exalgo, yeah.
Q. Okay. And the -- at the top there's -- you're included in an email copied about an invite to the meeting tomorrow.
A. Uh-huh.
Q. Do you recall a meeting on the FDA's responses to Covidien's submission of REMS for Exalgo?
A. I do.
Q. And did it take place in St. Louis?
A. I don't remember.
Q. Okay. And who all do you recall being at the meeting?
A. Various people who are involved in the formatting, the resubmission, the regulatory. It was a cross-functional group of many people in the organization.
Q. Given the slide show presentations I've seen, and your earlier testimony, you held a pretty high perch in the REMS for Exalgo world --
A. I did.
Q. -- within Covidien?
A. I did.

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Q. Do you recall there being any dissension or blame given at the meeting to discuss these?
MR. DAVISON: Objection to form.
THE WITNESS: I don't understand the question.
MR. SAMSON: Sure.
Q. One can go to a business meeting, and it will be a very cooperative meeting of however many people are there to come up with a response to an outside agency's criticism of some project that the company has done. You've been to meetings like that, I assume?
A. I have.
Q. And there are other meetings at which there's blame and dispute and disagreement on how we're going to respond. Do you -- you've been to meetings like that?
A. I have.
Q. Do you recall whether this meeting, about starting to respond to what the FDA had responded to the submitted REMS, was one or the other?
A. So the tenor in this meeting was a lot of excitement and a lot of interest to prepare a

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high-quality response as soon as possible.
Q. Okay. And you read then, and I think you have read it again today, the FDA's response.
It's true that REMS are supposed to fully and fairly explain the risks and benefits of the drug to prescribers, pharmacists, caregivers, and patients? That's the goal?
MR. DAVISON: Objection to form.
THE WITNESS: The goal -- you're reading point 8 there on page --
BY MR. SAMSON:
Q. No, I was just reading -- that was just a general statement.
A. Oh. The goal is to -- there are two goals of the REMS: To inform patients and providers about the potential for abuse, misuse, overdose and addiction of Exalgo; and, two, to inform patients and providers about the safe use of Exalgo in opioid-tolerant patients. Those are the two goals of the REMS.
Q. Okay. They are not -- REMS are not intended to be promotional vehicles?
A. Absolutely not.
Q. And that was certainly in keeping with your personal goal and Medical Affairs goal of

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presenting science and medicine-based, evidence-based decision-making; true?
A. Yes. Yes.
Q. And promotion in marketing doesn't belong in that either?
MR. DAVISON: Objection to form.
THE WITNESS: They don't belong in that to -- to create any content or to influence content. But they have to be aware of what's coming because their sales rep and their marketing program has to be such that it's promoting a product with a REMS. They can't do anything against, in violation, or contra against what the REMS is calling for.
BY MR. SAMSON:
Q. Okay. Turn in the FDA's response to boldfaced B, "Specific Comments." And in number one the FDA said:
(Reading) There's concern that the proposed REMS materials minimize the risks of Exalgo by omitting the REMS-specific risk information within the body of the letters and the brochure (end of reading).
Do you see that?
A. Could you tell me where you're

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reading again. Oh, this stuff.
Q. B-1.
A. I see it now.
So this is -- there is the FDA going to school on what we submitted and providing guidance on how they want it changed.
Q. And they thought that how you submitted or didn't submit, omitting REMS-specific risk information within the body of the -- are those patient letters or physician letters?
MR. DAVISON: Objection to form.
THE WITNESS: There's no patient letters. There's letters to prescribers, pharmacies, and professional associations. Yeah.
MR. SAMSON: Okay.
THE WITNESS: They wanted it strengthened.
BY MR. SAMSON:
Q. They wanted the risk sharing strengthened in your letters to match the label?
A. Right. Right.
Q. Okay. And, in general terms, minimizing the risk of a medication would be expected to make it -- make more physicians want to prescribe it because it has lower risk?
A. Uh-huh.

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MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. Is that a "Yes"?
A. That's a yes.
Q. Okay. And the FDA wanted Mallinckrodt to change that about the REMS for Exalgo?
A. They did.
Q. Okay. (Reading) Number two, the proposed REMS materials present the claim, quote, the adverse event profile of once daily Exalgo is typical of strong opioids, period, end quote. The proposed claim minimizes the risks associated with Exalgo therapy (end of reading).
A. Eliminate this language.
Q. So the same thing as number one, a criticism that the drafted REMS from Mallinckrodt minimized or understated the risk, and that might lead to inadvertent overuse on the part of physicians?
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. True?

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A. The FDA wanted us to change stuff in the document. We're going to do exactly what they want.
Q. Do you see any other reason, other than misleading physicians into underestimating the risk, because the risk hasn't been spelled out in the REMS materials for them, the FDA wanting this change?
MR. DAVISON: Objection.
BY MR. SAMSON:
Q. Number two --
MR. DAVISON: Objection to form.
THE WITNESS: I see the thing that was going on here, is this was plowing new ground for our company. This was the first REMS that they ever submitted. They don't have experience in doing it. I didn't have experience in doing it. So we were feeling our way along.
And that's why the FDA has a review process. And whatever their specific comments are is exactly what we're going to do.
BY MR. SAMSON:
Q. And then, number three:
(Reading) The content and order of presentation of the risk information within the proposed REMS materials

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minimizes the risks associated with Exalgo (end of reading).
And then they gave you an example of presenting the most commonly reported adverse offense on page 1, while the boxed label or warning -- label warning isn't -- is presented on page 3 after the signature line.
A. Right. This is a format issue. They prefer a format that puts the box warning more up front, which is fine with me.
Q. Did you draft these REMS?
A. No. No. I provided some oversight.
This is the first REMS creation of an opioid, long-acting opioid REMS that I was ever involved with. And we took our best shot. That's why the FDA has a review process, to keep everybody on the straight and narrow.
Q. Commonly reported adverse events, what would those have included in Exalgo?
MR. DAVISON: Objection to form.
THE WITNESS: I don't recall.
BY MR. SAMSON:
Q. Constipation?
A. That's a typical opioid side effect.
Q. And that is a commonly -- common one?

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A. It is. Nausea and vomiting.
Q. Nausea and vomiting. Any others that would have been put on page 1?
MR. DAVISON: Objection to form.
THE WITNESS: Somnolence. Drowsiness would be commonly reported side effects.
BY MR. SAMSON:
Q. And the black box warning would have addiction, overdose, death, respiratory depression; correct?
A. Correct.
Q. And so those, for want of -- in a layman's terms -- scarier risks are on page 3, and the most common, but not really all that life-threatening risks, are put on page 1; that's what happened --
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. -- as you read this?
A. It seems so. But we changed it.
Q. Okay. Because the FDA made you?
MR. DAVISON: Objection to form.
THE WITNESS: The FDA requested that we did it, and we did it.
MR. SAMSON: Okay.

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THE WITNESS: They were right.
BY MR. SAMSON:
Q. No. 4:
(Reading) Mallinckrodt, in its draft, left out the specific part of the indications on the label that it wasn't for -- Exalgo was not for acute pain, mild pain, or pain that wasn't expected to persist for an extensive period of time (end of reading).
True?
A. That's what it says here, yeah. It's not for those patients.
Q. Okay. And the effect of that, not putting in those specific "Don't use it for A, B, and C," is to potentially leave patients or prescribers ignorant of the fact that it's not for those reasons?
MR. DAVISON: Objection to form.
THE WITNESS: No, you have to tell -- you have to tell them what it's indicated for.
BY MR. SAMSON:
Q. And in this instance, what it's --
A. Not.
Q. -- specifically not indicated for --
A. It's always best.

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Q. -- if the FDA in your label says you need to mention these, not uses in your label; true?
A. True.
Q. And, again, Mallinckrodt submitted it without the "don't use it for these things" part of the label?
MR. DAVISON: Objection to form.
THE WITNESS: Apparently.
BY MR. SAMSON:
Q. Number five and number seven, the FDA decided that those two were promotional in tone?
A. Yeah, they didn't like the word "pleased." That's not something you say in a regulatory communication.
Q. And that was in number five; right?
A. Uh-huh.
Q. And then what about in seven?
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. I will read it to you:
(Reading) Remove the second paragraph of the letters. These claims and presentation are promotional in tone and focus on promoting the benefits of the treatment rather than on educating

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about the serious risks of treatment, period (end of reading).
A. Uh-huh.
Q. And, again, when you looked at this, you agreed that the FDA was right to say --
A. Totally right.
Q. -- to take it out?
A. The standard of performance in a sales presentation is a balanced presentation, risks and benefits. That's not the standard here. It's only risks that are presented, not benefits.
Q. Well, and to put benefits in under those rules is to promote?
A. Yeah, that's the way the FDA looks at it. And they are completely correct.
Q. Okay. And then if we go to number eight in the D Section, there was a text box on top of the letters, apparently?
A. I don't remember the letters. But if they say there was, there was.
Q. And the presentation of the information within the box has a header, "Minimizes the REMS risks associated with Exalgo."
And, again, the FDA in REMS didn't accept what it viewed as Exalgo's drafting or layout that

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tended to minimize the risks?
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. True?
A. They requested changes, and we made the changes.
MR. SAMSON: Let's move to -- I will take a wild guess -- 18.
THE REPORTER: Yes.
THE WITNESS: Are we done with this one?
MR. SAMSON: Yes. Unless somebody else may have questions of you about it.
(Exhibit No. 18 was marked.)
MR. SAMSON: That's it.
Counsel, this one is, as you'll see, is not Bates consistent. I wanted to just keep the number of exhibits to a minimum. There's a -- the first page of Exhibit 18 is a stand-alone exhibit that just came out of the documents as the suspicious ordinary monitoring team charter.
The other one -- the rest of the pages of this exhibit are from a different document in the production.
And then let me give him, because it will come to a question about it, 19. That will be 19.

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(Exhibit No. 19 was marked.)
(Witness reviewing document.)
BY MR. SAMSON:
Q. Ready, Mr. Morelli?
A. I'm ready.
Q. All right. This is -- the first page of 18 is a Suspicious Order Monitoring Team Charter, and it shows as of updated 4-7-11 -- right next -- under the charter.
A. Yep.
Q. -- that you were listed as a member of the Suspicious Order Monitoring Steering Committee as of April 7, 2011. Was that true?
A. That was true.
Q. Okay. When were you appointed to that team?
A. I don't recall. But during my stay at Mallinckrodt. I mean --
Q. Were you on it when you were a consultant?
A. Oh, no. No.
Q. Okay. So sometime after the end of October, 2009, up to April of 2011, you would have become a member?
A. Probably.

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Q. Okay. Before being appointed to the Mallinckrodt Suspicious Order Monitoring Team, had you ever served on a Suspicious Order Monitoring Team before?
A. No.
Q. Ever had any contact with that in the pharmaceutical business, suspicious order monitoring?
A. I was aware it existed. I was never involved with it directly.
Q. And what was your basic understanding?
A. Well, my basic understanding is the whole supply chain process is an opportunity to limit diversion. Now, diversion is not within a REMS program, because diversion is not an FDA program. It's a DEA program. But it's still important.
So that's -- that's my -- that's how it involved me. Because if it improves safety, I'm interested in it.
Q. And does safety involved in reducing diversion, may not be to an individual patient being prescribed medications and taking it that has safety aspects around it, but the public safety?
MR. DAVISON: Objection to form.
THE WITNESS: The public safety, yeah.

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BY MR. SAMSON:
Q. Do you recall how you were appointed or by whom to the Suspicious Order Monitoring Team?
A. It would have had to be Herb Neuman.
Q. Do you remember replacing someone else from Medical Affairs?
A. No.
Q. Did you ever learn that we always had somebody from Medical Affairs on the Suspicious Order Monitoring Team?
A. I don't recall that, no.
Q. Okay. And it looks like the steering committee, which is where you show up, had once-a-quarter meetings?
A. It sounds right, yeah.
Q. Does that fit with your memory?
A. It fits with my memory.
Q. Do you have a memory of how many times you remember going to the suspicious order monitoring quarterly meeting?
A. Maybe two -- maybe two or three times. Yeah.
Q. And I don't see anybody else from Medical Affairs that was on it, at least at this point. Was there ever any other -- when you were on

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the team, was there any other Medical Affairs person?
A. Not to my knowledge, no. And there are none from this list that were Medical Affairs.
Q. Okay. What was your job or role on the Suspicious Order Monitoring Team, if any?
A. My role was to make the Suspicious Order Monitoring Team aware of what we were doing on the REMS side and the safe use side so they would have awareness of that, and how it's relevant to the overall vigilance of the company, how it fits with the vigilance of the customer, of which the suspicious order monitoring system is one program for, you know, proper vigilance.
Q. Okay. And explain to me how you explained to them that suspicious order monitoring and accurate REMS, in the case of Exalgo, fit together into one goal?
MR. DAVISON: Objection to form.
THE WITNESS: What I was trying to impress upon the team is the need for granularity of data.
For example, drug distribution data to a wholesaler or a warehouse might be interesting but not particularly helpful. Whereas, drug -- opioid distribution to an individual pharmacy is much more helpful.

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So, as I remember, we sometimes had access to that level of detail, and sometimes we didn't. And what that would show is an individual pharmacy in X, Y, Z ZIP code of the United States would have a -- sort of an out-of-profile order, where they would order ten, ten, ten, they would order a hundred, then ten, ten. So why did they order a hundred? It could be completely innocuous. We don't know.
But then we're going to -- if we know that, then we can go back to what the prescription data is, which is ZIP-code based, and see if there's any correlation. We can go back to reports of pill mills and reports of other suspicious activity because we know who's prescribing and what they are prescribing.
So if we see -- if we see a dermatologist prescribing massive amounts of opioids, we're going to look into that. We're not going to just let that lay. Or if we see a surgeon, to give an example, a surgeon prescribing Exalgo, that's a big problem. We have to look into that.
So having more data gives us more information and more insight.
BY MR. SAMSON:
Q. And did you -- were you a voice for more data, get whatever we can to show where our

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drugs are going?
MR. DAVISON: Objection to form.
THE WITNESS: I did -- I did deliver that message. But people -- people generally got it. They understood it, why they were doing what they were doing.
BY MR. SAMSON:
Q. Okay. And I think you've answered this indirectly by what you were talking about, you know, a pharmacy, that's been ordering ten bottles, ten bottles, ten bottles and then orders a hundred bottles.
Do you recall, while you were on the Suspicious Order Monitoring Team, that there were triggers of purchase by, be it a clinic buying directly or a distributor or a pharmacy, that would trigger what was called a peculiar order?
MR. DAVISON: Objection to form.
THE WITNESS: I don't recall that, no.
BY MR. SAMSON:
Q. Okay. And peculiar orders would then be looked at more closely to see if there was a reasonable explanation for why it doubled; do you recall that?
MR. DAVISON: Objection to form.

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THE WITNESS: I mean, that's the principle upon which suspicious ordering is based. But I don't recall it happening, quite frankly. It may have happened, but I don't recall it happening.
BY MR. SAMSON:
Q. Okay. Do you recall that prior to April 10th of 2010, Mallinckrodt had a [redacted] -- [redacted] of the monthly order of the previous years as the triggering event?
A. No.
MR. DAVISON: Objection to form.
THE WITNESS: I wasn't aware of that.
BY MR. SAMSON:
Q. And having served on the Suspicious Order Monitoring Committee -- and I will ask you to assume that at one point Mallinckrodt did have a [redacted] purchasing trigger point for peculiar and then suspicious order investigation. Can you make that assumption for me?
MR. DAVISON: Objection to form.
THE WITNESS: Is it a hypothetical or what?
MR. SAMSON: Yeah.
THE WITNESS: Okay.
BY MR. SAMSON:
Q. Since you don't know that that's what

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it was.
A. Yeah.
Q. Assuming that to be true, do you see any reason, based on your years in the pharma industry or your service on the Suspicious Order Monitoring Team in the time you were at Mallinckrodt from 2009 to 2011, when, as you put it, there was a huge opioid problem, that it would make sense for the Suspicious Order Monitoring Program to increase the trigger to three times?
MR. DAVISON: Objection to form.
THE WITNESS: So here's -- here's how I look at it. You asked me based on my overall experience, not specific in-depth suspicious order monitoring experience or knowledge. You're asking me just as a principal, of a pharmaceutical person.
MR. SAMSON: Yes.
THE WITNESS: If -- if it was all going up in concert, in terms of the distribution data, more or less going up like this, kind of a mass effect, I would be concerned. But I would be less concerned than the increase was a spike of increase here and a spike of increase here and low here. You know, staccato kinds of increases would really alert me because that means, what's different about these

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areas.
Because what I know -- I'm giving you the value of my experience now. What I know is there's regional hot spots with abuse and misuse and addiction and overdose. It's not uniform across the country. There's hot spots and there's cold spots.
BY MR. SAMSON:
Q. Were you aware, during your time at Mallinckrodt, that for opioid abuse or use or overuse, Florida was a hot spot?
MR. DAVISON: Objection to form.
THE WITNESS: Yes. Because of pill mills.
BY MR. SAMSON:
Q. And what other hot spots geographic did you become aware of for the opioid pain space?
A. West Virginia. Kentucky.
Q. How about Ohio?
A. Ohio never stood out in my mind, no, for some reason.
Q. Okay. Which other ones, then, did?
A. Did I say Kentucky?
Q. You did.
A. Okay. Kentucky, West Virginia, Florida. Those would be the main ones that would stick out in my mind.

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Q. Okay. I'm assuming that you don't recall being around when the trigger point went from [redacted] previous annual monthly sales to [redacted]

MR. DAVISON: Objection to form.

THE WITNESS: I'm not even sure what trigger point is. And I was not around when that happened. I was not even aware it happened.

BY MR. SAMSON:

Q. I'm calling it a trigger point. But basically you've sort of identified yourself that what you're doing in suspicious order monitoring is looking at patterns and amount of purchase?

A. Right. Right. That's exactly what it is.

Q. And then you've got to have some level at which you say, I'm going to call this amount two times as much --

A. I see.

Q. -- as the year before not likely to just be variation that goes on in a -- all lines are -- very few lines are straight, and they are going to be going up and down day by day and week by week, but if it gets to [redacted], then I'm going to look into it; do you recall that?

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A. No, I don't recall.

MR. DAVISON: Objection to form.

BY MR. SAMSON:

Q. And you certainly don't recall that going from [redacted] to [redacted]?

A. No.

Q. Okay. Assume that there is some trigger or purchase level that would cause Mallinckrodt's Suspicious Order Monitoring Committee to call it a peculiar order and ask that it be looked into. Okay?

MR. DAVISON: Objection to form.

BY MR. SAMSON:

Q. That's a hypothetical. Yes? Can you make that assumption?

A. Yes. A hypothetical. If you're making it a hypothetical, yes.

Q. Would you send, based again on your experience in pharma, a member of the sales team or marketing team to determine whether or not the order should be cleared?

MR. DAVISON: Objection to form.

THE WITNESS: I would not, no.

BY MR. SAMSON:

Q. Why not?

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A. Because they are not qualified to make that determination. They are not senior enough to make that determination. And, you know, I would send someone who has knowledge and experience in the area, and someone has a relationship with the wholesaler -- wholesaler people. Because they know where they sell stuff to. So I would rely on my relationship with the wholesalers.

In my experience, wholesalers are always willing to help their customers, because we're a customer. So they are willing to help us, if it's a reasonable request. That's why we have people in wholesaler relations that have a long-standing relationship with wholesalers, so they can communicate with one another.

Q. And would you let those wholesale relationship people -- how do they build that relationship, in the --

A. They --

Q. -- sales relationship with the wholesalers?

A. It's a --

MR. DAVISON: Objection to form.

THE WITNESS: It's a transactional relationship. It's a contractual relationship. It's

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a long -- you know, tend to be longer-standing relationships. And, you know, like any other business relationship, there has to be a high degree of trust.

And based on that, and I would -- I would have a sit down with them and see what we can -- how we can get inside this problem, to find out if it's really a problem. Because maybe some other area has gone -- dropped, you know. Because Dr. Lipschitz, who was a big prescriber moved over to this one and he left that one. So, you know, it's this kind of thing. But I don't know. You have to look at the data.

BY MR. SAMSON:

Q. Okay. And do you recall ever being told about or looking at the data of suspicious order monitoring claims that needed investigation going up or down in your time on the board or on the committee?

A. No, I do not.

Q. As far as you know, it was just flat --

MR. DAVISON: Objection.

BY MR. SAMSON:

Q. -- what you were getting from a

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quarterly meeting?
MR. DAVISON: Objection to form.
THE WITNESS: Basically. I didn't see any massive red flags, and certainly none on Exalgo. Because the volume was so low.
BY MR. SAMSON:
Q. Did you get reports, either weekly, monthly, quarterly, or anything about how suspicious order monitoring programs were working?
A. No.
Q. As a member of the board?
A. No, not that I remember.
Q. I keep calling it the board.
A. I know.
Q. The team.
A. The team, yeah.
Q. Okay. Now, decreasing diversion -- although, as you pointed out, not an FDA thing -- that was an important Covidien goal; true?
A. Very important.
Q. And across all the opioids, not just Exalgo?
A. From the C.A.R.E.S. Alliance perspective, absolutely across all the opioids.
Q. Okay. And let me ask you to look at

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Exhibit 19 --
A. Okay.
Q. -- which you also have there. And I will send you to -- it looks like I've got page 3 on it.
A. What does it look like?
Q. That's -- that's not it. No.
A. It looks like the back. Let's see what you're --
Q. This is, "Safe and Appropriate Use of Opioids from C.A.R.E.S. Alliance."
MS. GAFFNEY: It's the back page.
THE WITNESS: Yeah, I got it. I think I have it now.
BY MR. SAMSON:
Q. All right. Now, "Introducing C.A.R.E.S. Alliance."
A. Right.
Q. And there's a mission statement; right?
A. Yes.
Q. And then there are objectives. And read the first objective of the C.A.R.E.S. Alliance.
A. (Reading) To ensure responsible prescribing, dispensing, use and

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storage of opioid analgesics to avoid misuse, abuse, addiction, diversion, and overdose (end of reading).
Q. So diversion is and was important to Mallinckrodt?
A. Absolutely.
Q. Can you -- assuming that my hypothetical is right, and Mallinckrodt increased the increase of order necessary to cause investigation of the order, how that possibly helped reduce diversion?
MR. DAVISON: Objection to form.
THE WITNESS: I don't think it necessarily helped reduce or increase diversion. That's -- distributing drugs through a proper channel is not diversion. It's when they -- diversion is the possession of a drug by someone who is not authorized to possess it.
Wholesalers are authorized to possess it. Pharmacies are authorized to possess it. Patients who have been prescribed are authorized to possess it. Others are not. That's diversion.
BY MR. SAMSON:
Q. Okay. So what do you call the pill mill in Florida, where physician A is both dispensing and prescribing opioids as fast as he or she can just

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for the profit of it?
MR. DAVISON: Objection to form.
THE WITNESS: It's not diversion. It's a very serious problem. But technically it's not diversion. It's -- it's overprescribing and improper prescribing, is how I would characterize it. Yeah.
BY MR. SAMSON:
Q. And would that be something that Mallinckrodt had an interest, when you were there, in identifying and stopping, if it could?
MR. DAVISON: Objection to form.
THE WITNESS: We did. We did. And we did it, actually.
BY MR. SAMSON:
Q. And why do you say, "we did it"?
A. Because we had examples, and I can't remember where, of sales reps reporting -- and this is in the day of television quality pill mills. We all saw the videos, right. Sat there in disbelief at what we were watching. So it was fairly easy to identify, quite frankly.
So we -- part of our training of our reps -- because they are the ones that are going out there, they are the ones that are going to see these pill mills, to report that pill mill and to stay out of

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it.
Q. Okay. During your time as Vice President of Medical Affairs at Mallinckrodt, were you familiar with the phrase that an opioid manufacturer needed to, quote, know its customer, end quote?
MR. DAVISON: Objection to form.
THE WITNESS: The opioid manufacturer needed to know its customer. I never heard anyone say that, no.
BY MR. SAMSON:
Q. And you never heard, either, another phrase, "You don't only have to know your customer but also his customer"?
A. No.
Q. You would agree with me, though, that in terms of safety in the opioid space, to the extent Mallinckrodt had the ability to be aware of where its distributors' customers might be selling its opioids downstream, it would need to make use of that ability to find out where its drugs were going?
MR. DAVISON: Objection to form.
THE WITNESS: Oh, of course.
BY MR. SAMSON:
Q. All right. And also if it had the

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ability on data that it had within its possession and control, that it could use that to identify downstream clients that might be buying from multiple sources?
A. Which does happen.
Q. And would that be something that Mallinckrodt would be all over?
MR. DAVISON: Objection. Sorry. Objection to form.
THE WITNESS: It would be.
BY MR. SAMSON:
Q. Were you ever aware of something called charge-back data?
A. Yes.
Q. When did you become aware of that?
A. Oh, years and years and years ago.
Q. Prior to going to Mallinckrodt?
A. Oh, long before.
Q. And did you have any thought, while you were there, that Mallinckrodt probably had charge-back data that would give it insight into where the drugs -- its drugs were ending up?
A. No, I didn't. I had no involvement with the charge-back system at Mallinckrodt.
Q. Sitting here, and based on your

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knowledge from other pharmaceutical uses, what is a charge-back?
A. A charge-back is a way to price adjust for drugs that are sold at a certain price and then reimbursed at a lesser price to keep the system whole. So it's a credit that the pharmaceutical company issues.
Q. And in a -- say Mallinckrodt sells generic oxy to Cardinal at a given price.
A. Right.
Q. And then market factors influence that for Cardinal to sell it, it's got to sell it at a lower price, maybe even than it bought it.
A. Yeah.
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. And that's where charge-backs come into the pharmaceutical instrument; is that true?
A. That's right.
Q. And that means that Cardinal informs Mallinckrodt of the sale and how badly it got hurt, and Mallinckrodt then makes what's called a charge-back relief, so to speak, on what Cardinal owes for the drugs; right?
MR. DAVISON: Objection to form.

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THE WITNESS: Right.
BY MR. SAMSON:
Q. If we're dealing with opioids, when Mallinckrodt would receive charge-back data from a distributor, a customer of its, and received charge-back data from another distributor, it would have potentially a list of physicians or clinics who were buying from both distributors; true?
MR. DAVISON: Objection to form.
THE WITNESS: Not physicians. Physicians don't buy opioids. They prescribe them.
So the pharmacies would be purchasing the opioids from the distributor, and those prescriptions would be filled at those pharmacies.
BY MR. SAMSON:
Q. And --
A. Physicians cannot possess opioids unless they have a special license to possess them.
Q. Other than in Florida?
A. I don't know about Florida. Maybe Florida is weird. I don't know.
Q. They are a dispensing state where the physicians dispense.
A. Controlled substances?
Q. Oh, yeah.

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MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. Wasn't that one of the big fuelers of the Florida pill mills especially?
A. That's not how I looked at it.
MR. DAVISON: Objection.
BY MR. SAMSON:
Q. Well, assuming that Mallinckrodt had that charge-back data -- which it would have; correct?
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. From all of the places where it sold its drug on the distributor label -- level?
A. Probably --
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. And that charge-back data, the Mallinckrodt direct customer has to give it, Mallinckrodt, information about where those drugs went; correct?
MR. DAVISON: Objection to form.
THE WITNESS: So if we had the data of which pharmacies were buying which quantities of opioids, that would be overall useful in tracking down where

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problems are occurring. We have the prescription data already. We know who's prescribing. How much they are prescribing. We know their ZIP code. We know who they are. Okay. We already have that.
We don't have the patients, because we can't have patient information. But we know the prescriptions that are written by a given physician.
That's the most important information. It's more important than charge-backs, because it's even more granular, down to the physician level. So that empowers us -- I'm talking Exalgo now -- that empowers us to identify massive, you know, really large and kind of unexpected levels of prescribing or, even more importantly, prescribing activity by a physician specialty who you would not expect would be doing a lot of pain management, like a pediatrician. But the complicating factor is, physician specialties are recorded by their AMA specialty designation. So that's how they did their training. It may not be what they are practicing. Because they are still licensed.
So it's not so simple that you see a pediatrician prescribing Exalgo, and that's automatically a problem. It could be a pediatrician who is trained and now is a pain specialist.

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BY MR. SAMSON:
Q. Okay. Do you see any reason not to add charge-back data to that other data that you have from the prescriptions itself?
MR. DAVISON: Objection to form.
THE WITNESS: I don't think it's particularly helpful. But maybe I'm wrong. I'm not a data analyst. Maybe there's another way to cut this data that might be helpful. I just don't know.
BY MR. SAMSON:
Q. Well, if Mallinckrodt was truly a champion in eliminating the over-sale and overuse of opioids in the time that you were there, wouldn't you expect them to look into every possible way of identifying misuse by identifying where large amounts of their drugs were going?
MR. DAVISON: Objection to form.
THE WITNESS: That's what I would do. And that's what I did with Exalgo. And that was my area of responsibility. So that's what I will stand and swear to.
BY MR. SAMSON:
Q. Okay. And you did that because that was consistent with your view of the responsibilities of responsible pharmaceutical companies; correct?

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A. True.
Q. You didn't make that up as an Art Morelli code of honor; did you?
MR. DAVISON: Objection to form.
THE WITNESS: No, I did not.
BY MR. SAMSON:
Q. And you would expect any other responsible member of the pharmaceutical industry to do -- reach for the same goal that you were reaching for; true?
MR. DAVISON: Objection to form.
THE WITNESS: I think you will get feedback that I set very high standards when I worked at Mallinckrodt for the work that I was overseeing or personally doing.
BY MR. SAMSON:
Q. Let's look at --
A. Are we still on this slide deck here?
MR. SAMSON: No. You can put that away. And let me see.
MS. GAFFNEY: Can we go off the record for a second and get --
MR. SAMSON: Oh, get that. Okay. Let's go off the record.
THE VIDEOGRAPHER: We are going off the

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record. The time is 5:21 p m.
(Recess taken.)
(Exhibit No. 20 was marked.)
THE VIDEOGRAPHER: We are back on the record. The time is 5:30 p m.
BY MR. SAMSON:
Q. Mr. Morelli, you've got Exhibit 20 in front of you. And I will tell you, for the record, it's a portion, just to cut down on forest loss, of the entire presentation. And I wanted to turn your attention to the back page, which is headed, "Team Membership."
A. Uh-huh.
Q. And this is a list people in Medical Affairs in the first row; correct?
A. Yes. Yes.
Q. And it then says who does what on Strategy and Development Team, Exalgo Implementation Team, PENNSAID Implementation Team, and then Generic Products Implementation Team.
Who -- it says everyone in PPS is in on the Generic Products Implementation Team. Is that a REMS team, or what? What's being implemented?
A. Yeah, there were --
MR. DAVISON: Objection.

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THE WITNESS: There were certain generic products that had certain FDA requirements for certain things that we had to do. And that's -- that's what that was.
BY MR. SAMSON:
Q. And then PV, what part of Medical Affairs was that? I have forgotten if you told me.
A. Pharmacovigilance.
Q. And that was Danielle?
A. Eddie and Danielle. Danielle is a physician. Eddie is a pharmacist.
Q. But specifically for generics implementation?
A. Oh. Danielle, yeah.
Q. And that's, again, just to do with the REMS? That was all that you guys had to do with -- any generic that required REMS from the FDA?
A. So, yes. Elements of safe use, put it that way. Because this is so far back, some of these -- it was before REMS -- REMS came in in 2007. So it was pre -- pre-REMS, but it was still certain safe use elements that we had to do, yeah.
Q. Okay. But, I mean, 2007 you hadn't even arrived at Mallinckrodt?
A. Right. That's when the legislation

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came in. Yeah.
MR. SAMSON: All right. And now let me --
THE WITNESS: Are we done with this one?
MR. SAMSON: Yeah.
THE WITNESS: Oh, okay.
THE REPORTER: 21.
(Exhibit No. 21 was marked.)
(Witness reviewing document.)
BY MR. SAMSON:
Q. Are you -- have you read it, Mr. Morelli?
A. I have.
Q. This is an email string between yourself and Rod Hughes with some other CCs on it?
A. Yes.
Q. And the subject line from Mr. Hughes is, "Prescription Pain Killers, colon, Company's Attempt Abuse Proof Opioids, ABC News." Correct?
A. Correct.
Q. And then Mr. Hughes writes to JoAnna Schooler. Was she in Medical Affairs?
A. No. She's a communications person.
Q. (Reading) JoAnna, I am sure you have this, but I wanted to highlight this just in case. It is remarkable

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how Purdue has positioned their product as abuse proof. They did this by showing no data. The Exalgo deterrent abuse features are just as good, if not better, than Oxycontins. In fact, that tablet also uses Polyox as the excipient (end of reading).
Did I read that correctly?
A. You did.
Q. Was there Polyox in Exalgo?
A. I don't recall. But I believe there was.
Q. Okay. And what, as you recall, was the function of Polyox?
A. It was an excipient.
Q. Which means to?
A. It was a nonactive ingredient, but part of the formulation.
Q. And what -- what did Polyox add to the drug?
A. I don't really know.
Q. Did it make it more bioavailable?
A. I don't know.
Q. And you think Exalgo may have used it as well?

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A. It may have.
Q. Did it have any potential abuse deterrent reason to be in either Oxycontin or in Exalgo?
A. I don't know.
MR. DAVISON: Objection to form.
BY MR. SAMSON:
Q. All right. And your comment to what Mr. Hughes wrote to JoAnna was:
(Reading) Another reminder of who we are dealing with and why our industry has the problems it does. We must lead (end of reading).
A. Right.
Q. "We," Covidien?
A. Correct.
Q. "Who we were dealing with" was Purdue?
A. The industry in general, quite frankly.
Q. Okay. And why did you, Art Morelli, believe that in 2000 -- 2011 the industry, the pharmaceutical industry, or more narrowly the opioid pain space -- which one were you targeting?
MR. DAVISON: Objection to form.

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THE WITNESS: Well, this email was about the opioid pain space, but I was making a more general statement.
MR. SAMSON: Okay.
THE WITNESS: Not to exclude opioids, but to include them in that.
BY MR. SAMSON:
Q. And explain to me your phrasing of, "This is why our industry has problems"?
A. Well, I don't have the primary article here, so I really can't comment definitively on -- on that.
But the overarching statement is, you don't have an abuse deterrent indication. Don't try to position your product as abuse deterrent.
Q. Well, and from the Art Morelli who has appeared today, don't make that statement without showing data that supports it; correct?
A. But even if you have --
MR. DAVISON: Objection to form.
THE WITNESS: -- even if you have data, that's helpful, but it's not definitive. You have to have the indication to promote and position your product as abuse deterrent.
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BY MR. SAMSON:
Q. And so were you expressing your frustration in having to be in competition with a company who you thought ignored the principles of pharmaceutical safety and reporting?
MR. DAVISON: Objection to form.
THE WITNESS: Not so much, no. I would just think, rather than compare ourselves to other companies, we just know what's right, and we have to lead with what we know is right.
BY MR. SAMSON:
Q. And what was the industrywide problem that you were referencing?
MR. DAVISON: Objection to form.
THE WITNESS: Well, it's quite well known that the perception, the public perception of the pharmaceutical industry, is pretty low, and stunts like this can't possibly be helpful. That's what I was thinking of when I wrote this.
BY MR. SAMSON:
Q. And Mr. Hughes wrote back that he agreed?
A. Right.
Q. Did you ever sit down and have a discussion with Mr. Hughes --

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A. I don't recall.
Q. -- about this series of events?
A. I had many discussions with Mr. Hughes, but not -- not specifically about this, that I remember.
Q. When you decided to leave Mallinckrodt, part of it, you said, was not wanting to remain in St. Louis; correct?
A. It was. It was a big part. The biggest part, actually.
Q. Okay. You also, though, had -- were just into the -- not the launch, but the development of Exalgo; correct?
A. Oh, no, it was after --
MR. DAVISON: Objection to form.
THE WITNESS: -- well after the launch.
BY MR. SAMSON:
Q. And you put in the REMS?
A. Put in the REMS. The REMS was approved and in place. The C.A.R.E.S. Alliance was fully developed and launched, because it launched in 2010 at the Pain Week meeting. And the team was in place, established. And, you know, it's like, I guess, leaving it -- leaving it at your peak kind of concept.

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Q. How did Exalgo do? Did you keep track of your little baby after you left?
MR. DAVISON: Objection to form.
THE WITNESS: Very, very lightly, if not at all, you know. Maybe in a discussion on the phone with Herb here and there, but that would be -- that would be about it. I never saw data, or I never really had any insights, you know.
BY MR. SAMSON:
Q. Did you get enough information to determine whether or not it had been a hit drug or a so-so drug, or a drug that never quite caught on?
MR. DAVISON: Objection to form.
THE WITNESS: I can't comment on that. I don't know.
BY MR. SAMSON:
Q. Is it still on the market?
A. Genericized, yeah. That I do know.
Q. Genericized with the OROs or just as --
A. The OROs. Generic OROs.
Q. And what did you do immediately after leaving Mallinckrodt?
A. Immediately after Mallinckrodt, I worked with Paragon Rx, the REMS development company,

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on various REMS projects that they had throughout the industry. Especially, almost inclusively, with companies in California.
Q. Any of them opioids, those REMS that you were --
A. Yeah.
Q. -- getting together?
A. Yeah, they were.
Q. And were they branded opioids or were they generics?
A. Branded.
Q. Have you ever had discussions of going back to work for Covidien?
A. No.
Q. Has anyone else, that you had a good working relationship, left Covidien and spoken to you about it?
MR. DAVISON: Objection to form.
THE WITNESS: No.
BY MR. SAMSON:
Q. You said that you had -- and maybe I overheard it -- talks with Art [sic] Neuman, that you would have brought something up if you knew about it. Have you had discussions with -- is he Dr. Neuman?
A. I've had many discussions with

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Dr. Neuman. I've had many interactions with Dr. Neuman. And I've worked with Dr. Neuman or subsequent projects.
Q. Okay. What have you worked with him on?
A. The Ohio State Initiative for Cancer. At Enlyton, the Advanced Cancer Imaging Company. I think those are the only two. And both of those are kind of long, long duration kind of engagements.
Q. Is Mr. Neuman still at Covidien?
A. Oh, no. He left after I did, but soon after.
Q. Did you ever trade stories about your days at Covidien with Dr. Neuman?
A. Sorry. That's privileged and confidential.
Q. That's a new privilege that's not recognized, but --
A. We -- we're friends. We're friends. Our wives, our families, we're friends.
Q. So I am assuming that you did have talks with him in which you said -- unless you had no frustrations during the time when you were at Covidien -- here's what I couldn't take, or here's what drove me crazy when I was at Covidien, telling

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it to Dr. Neuman?
A. Very little --
MR. DAVISON: Objection to form.
THE WITNESS: Dr. Neuman moved to California from St. Louis. So we became, you know, closer to each other on the map. So there was more potential to interact with each other.
He's in the Bay Area. But his wife is a doctor. So we have a lot in common, and we're just close friends. And, you know, whenever you work anywhere, there's always frustrations. But that -- I'm at a level of experience where I can kind of roll with the punches, so they don't bother me so much.
BY MR. SAMSON:
Q. Having mentioned and spoken to you today, it is, as you said in an earlier answer, that you had a very high principle. And one of the things that I take away from being able to ask you questions today, is that your personal approach to safety was, it was an all-or-nothing, bottom-line thing that pharmaceutical companies needed to address, especially in the opioid space.
Did I get that right?
A. I tried to do that --
MR. DAVISON: Objection to form.

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THE WITNESS: I tried to do that to the best of my ability, yes.
BY MR. SAMSON:
Q. And was there ever any frustration that Covidien was not as ardent about that as you were?
MR. DAVISON: Objection to form.
THE WITNESS: I wouldn't -- I would say, no. Whenever you're at a company and you're managing projects that are big, expensive projects, there can always be the potential for the feeling that, you know, well, are they going to continue? That's just the normal operations of things.
But Covidien -- what I was doing was supported by Herb and the CEO, Tim Wright. I always felt like I had really good support and belief in the importance of what we were doing. So there were very little on the frustration scale, quite frankly.
BY MR. SAMSON:
Q. And what you were doing, during the time you were an employee, was all, if not exclusively, greatly the majority in Exalgo; true?
A. It was, yeah.
Q. And the --
A. And the C.A.R.E.S. Alliance.

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Q. And you can't tell me, haven't been able to tell me today, much about what was going on in the generic opioid space, even with Mallinckrodt; true?
A. I had very little interaction, awareness, knowledge, with the generic business and the people in the generic business.
MR. SAMSON: Let's go off the record for just a second.
THE VIDEOGRAPHER: We are going off the record. The time is 5:28 p.m. -- or 5:48 p.m.
(Recess taken.)
THE VIDEOGRAPHER: We are back on the record. The time is 5:51 p.m.
EXAMINATION
BY MS. HERZFELD:
Q. Good afternoon, Mr. Morelli. How are you doing?
A. Fine. How are you?
Q. Great. I am Tricia Herzfeld, and I am an attorney representing the plaintiffs in Tennessee.
Do you know anything about the Tennessee litigation?
A. No.

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MS. HERZFELD: Okay. Before we get started, I just want to lodge our usual objections as to late production of documents in noncompliance with the MDL protocol, and the other objections that we have lodged in the other depositions. I would like to renew them at this time.
MR. DAVISON: We disagree with your characterization regarding our compliance with the MDL protocol. We have complied. But we note your objection.
MS. HERZFELD: Okay. Great. Now we will move on.
Q. Okay. So you don't have any awareness of the Tennessee litigation; do you, sir?
A. I do not.
Q. Okay. And you've been to Tennessee before; is that correct?
A. I have been to Tennessee.
Q. And how many times would you say you've been?
A. I've been to Tennessee once in my life.
Q. Okay. And was that for work?
A. No.
Q. What was it for?

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A. My daughter's swim meet at the University of Tennessee when she swam at Arizona State.
Q. Oh, okay. Very good. You haven't been to Tennessee for work?
A. Pardon me?
Q. You have not been to Tennessee for work?
A. No.
Q. Okay. When you were talking earlier about hot spots for pill mills, you mentioned Florida, obviously, and then Kentucky and West Virginia.
Would you consider both of those states to be in Appalachia?
MR. DAVISON: Objection to form.
THE WITNESS: I don't know really.
BY MS. HERZFELD:
Q. Okay. I'm --
A. I think they might be, but, you know --
Q. I will rephrase the question.
Would you consider to Kentucky and West Virginia to both be states contained within Appalachia?

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A. Yes.
Q. Okay. And would you consider Tennessee to be part of the Appalachian region?
A. No.
Q. Have you heard at all of pill mills being a hot spot in Tennessee?
A. I have not. No.
Q. Do you recall having any conversations with anyone about a particular opioid abuse problems in Tennessee?
A. I do not.
Q. Do you know what neonatal abstinence syndrome is?
A. I do.
Q. And what is it, to your knowledge?
A. Neonatal abstinence syndrome is a condition where a newborn goes through opioid withdrawal because they were exposed in utero to the mother's consumption of opioids.
Q. And do you know what region of the country has the highest number of any as per?
A. No. But I bet you're going to tell me.
Q. I'm asking if you know. Do you know?
A. No, I don't.

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Q. Have you ever known?
A. No.
Q. Is that information you've ever endeavored to obtain?
A. No.
Q. Would you be surprised to learn that Tennessee is number two?
MR. DAVISON: Objection to form.
THE WITNESS: I would be neither surprised or disappointed or anything. It is what it is. The data is what it is.
BY MS. HERZFELD:
Q. It probably isn't is what it is, though, for those babies?
A. No.
MR. DAVISON: Objection to form.
THE WITNESS: It doesn't minimize it at all. It's a terrible thing.
BY MS. HERZFELD:
Q. Have you ever seen videos of babies going through withdrawal of opioids after being born?
A. I have. I have seen some videos because of my work at DuPont with Narcan and Narcan neonatal, which is used in that setting. Yeah.
Q. And how would you describe watching

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those videos of the babies after they are born?
MR. DAVISON: Objection.
THE WITNESS: Ghastly.
BY MR. SAMSON:
Q. Ghastly?
A. Ghastly.
Q. Do you think they are in pain?
MR. DAVISON: Objection to form.
THE WITNESS: Don't know. But they are in distress certainly.
BY MS. HERZFELD:
Q. You knew that there was an opioid epidemic specifically in Florida; is that correct?
A. No, it's not exactly correct. I knew there were a lot of pill mills. The pill mills that I was aware of were in Florida. And there was an opioid epidemic -- you know, the opioid problem was more pervasive than just Florida. Yeah.
MS. HERZFELD: Okay. And I'm going to show you -- what number are we on for exhibits?
THE REPORTER: 22.
MS. HERZFELD: We will this mark as No. 22.
(Exhibit No. 22 was marked.)
BY MS. HERZFELD:
Q. Okay. Mr. Morelli, what I have

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handed you here appears to be an email from a person named Chris DuFusco.
Do you know who Chris DuFusco is?
A. I do.
Q. And who is Chris DuFusco?
A. He is an employee at Mallinckrodt in the -- I think in the Business Development, I think is what he was in when I was there.
Q. Okay. In Business Development did he handle any of the opioid products?
A. No.
MS. HERZFELD: Okay. And just for the folks on the phone and the record, the Bates number on this is MNK-T1, underscore, 0006317909. It's a one-page document.
Q. And what is the date on this email, Mr. Morelli?
A. 3/29/10.
Q. And this email is sent to Debra Hasse -- is it Hasse? Hasse?
A. Hasse.
Q. To you and to David Silver; is that right?
A. Right.
Q. And who is Debra Hasse?

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A. She was a coworker of Chris DuFusco.
Q. Okay. And so she was a Mallinckrodt employee?
A. Yes.
Q. Okay. And David Silver?
A. He was the -- Debra and Chris reported to David Silver.
Q. Okay. And so David Silver was also a Mallinckrodt employee.
A. He was.
Q. Okay. And this email was sent to the three of you on March 29th, 2010; is that correct?
A. That's correct.
Q. Okay. And do you have any reason to think that this email wasn't sent to your email address?
A. No. I'm sure it was.
Q. Okay. And what -- could you read the subject for me there, please.
A. Speak -- oh, the subject. "A news expose -- OxyContin Florida and Tennessee."
Q. And then what does the email say?
A. (Reading) I was speaking to one of the folks I met from Grunenethal in Portugal in the training class in

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Barcelona last week about our pain products, and he mentioned a news expose about the problems with the abuse of Oxycontin in Florida and Tennessee, and I thought you might find it interesting (end of reading).
Q. And then do you speak Spanish at all?
A. I do not.
Q. Okay. And so underneath that it says "Titulo," right, "Oxy Express"? Is that what it says?
A. "Titulo: Oxy Express - Repeticao."
Q. Okay. Very good.
And so do you know why it is that Chris would have sent an email specifically to you, David and Debra?
MR. DAVISON: Objection to form.
THE WITNESS: No, I don't know why he sent it.
BY MS. HERZFELD:
Q. Okay. And did you respond to this email?
A. I do not recall.
Q. Do you know if you ever had any conversations with anyone where you looked into an

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oxy abuse program -- or an oxy abuse problem in Tennessee?
MR. DAVISON: Objection to form.
THE WITNESS: I do not.
BY MS. HERZFELD:
Q. Okay. But according to this email, which is 2010, at the very least, then, you had received information about the Oxy Express involving Florida and Tennessee; is that an accurate statement?
MR. DAVISON: Objection to form.
THE WITNESS: I received this, yeah, and maybe other things that I was exposed to along the way, yeah.
BY MS. HERZFELD:
Q. Okay. But at the very least, you received this in 2010?
A. I did. I guess I did, yes.
Q. Okay. And can you think of anything else you might have been exposed to along the way that would have alerted you to an oxy abuse problem in Tennessee?
A. Just news releases, perhaps.
MS. HERZFELD: I am going to show you what we will mark as the next exhibit, 23.
(Exhibit No. 23 was marked.)

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MS. HERZFELD: For folks on the phone, this is MNK, hyphen, T1, underscore, 0007200216. And it's a -- one, two -- three-page document.
Q. Okay. Mr. Morelli, have you had a moment to look over this email?
A. Yes. Generally, yes. Not in detail. But yes.
Q. Okay. Let's kind of just go through it for one second. I'm not going to ask you to know everything in it.
Does this appear to be an email that was sent from a person named Stephen Littlejohn to you on February 19th, 2011?
A. Yes.
Q. Okay. And it also copies JoAnna Schooler; is that right?
A. That's right.
Q. And do you have any reason to believe you didn't receive this email in the ordinary course of business?
A. No, I don't.
Q. Okay. And so the subject here is, "Re: WSJ - Fight Over a Fix for Florida Pill Mills."
Do you see where it says that?
A. Yes.

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Q. Okay. And who is Stephen Littlejohn?
A. Stephen Littlejohn is a -- what is the VP of the Communications Department.
Q. For Mallinckrodt? For Mallinckrodt?
A. Mallinckrodt, yeah.
Q. Okay. And who is JoAnna Schooler?
A. She works in Littlejohn's department.
Q. Okay. So also a Mallinckrodt employee?
A. Yes.
Q. Okay. And so if you look at the email that's being forwarded, it looks like it says, "From JoAnna," kind of mid where the page is:
(Reading) FYI, more on the issue in Florida and the ongoing state funding debate. Will make contact with a reporter (end of reading).
And that's sent to a whole bunch of folks. Do you see that?
A. Uh-huh.
Q. Is that a "Yes"? Is that a "Yes"?
A. That's a "Yes," yes.
Q. Sorry. I have to get you to say "Yes" because "uh-huh" doesn't work on the transcripts.

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And then it looks like you reply on -- at 8:50 in the morning and say, it looks like, just shortly -- shortly there later -- and could you read your response to JoAnna there.
A. Yes. (Reading) This article brings out some excellent points pro and con of PMPs. The problems remain, however. I see here a way for us to bring in a best practices orientation rather than a good or bad approach and an idea of changing the dialogue from problem identification and blame to solutions. We need to contact Keith Humphreys, the Stanford PMP researcher named in the article. Bobby and I can do that. Bobby is someone who works for me. Do you agree (end of reading)?
Q. Okay.
A. And I reiterated, education, collaboration, innovation, which is a strategy for the C.A.R.E.S. Alliance.
Q. Okay. And so did you ever reach out to the Stanford PMP researcher named in the article, Keith Humphreys?

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A. I don't recall doing that, no.
Q. Okay. And do you know if Bobby did?
A. I don't know.
Q. Okay. Okay. And then if you will go down and actually read the article, get to the second page here. You believe, based on your email response to this, that you did read this article, is that right, sir, at the time?
A. I believe I did, yeah.
Q. Okay. So I'm just going to kind of bring you to some of those -- the more pertinent points --
A. Okay.
Q. -- that I'm going to ask questions about.
The very first line in the article says, "Dateline Miami"; do you see that? On the second page.
A. Yes.
Q. Okay. (Reading) Florida Governor Rick Scott called to cancel a state drug monitoring program starts an uproar in Appalachian state, the state that say that they're deluged with illegally bought pills from South

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Florida pain clinics (end of reading).
Do you see where it says that.
A. Uh-huh. Uh-huh.
Q. Is that a "Yes," sir?
A. It is, yes. I see it.
Q. And so was there a concern from Mallinckrodt about the PMP state drug monitoring program?
MR. DAVISON: Objection to form.
THE WITNESS: I can't speak for Mallinckrodt. But I can tell you that I'm very -- I would be very concerned about the cancellation of any PMP program. I'm very concerned about the lack of utilization of PMPs around the country.
MS. HERZFELD: Okay.
THE WITNESS: And the delay, the various problems with PMPs, that's one reason they are not utilized, and they are underfunded, and they have problems with their data and speed of updating, and that's a barrier to adoption for physicians. So they are potentially a very valuable tool.
BY MS. HERZFELD:
Q. Okay. And then if you will move down with me a little bit further. It says, "Jason Henry, for the Wall Street Journal." About halfway.

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Do you see there?
A. No. Where are you? Where are you?
Q. That's okay.
A. Oh, I see. The next one.
Q. Right there. Okay.
And then if you kind of keep going down, it says:
(Reading) Pill mills have flourished in Florida, especially in Broward County, in recent years. Weak standards governing who can set them up, a lack of oversight by state agencies, and the absence of prescription monitoring programs have contributed to the problems, said Sherry Green, Chief Executive of the of the nonprofit National Alliance For Model States Drug Laws (end of reading).
Did I read that correctly?
A. Yes.
Q. Do you agree with that?
A. I agree with that.
Q. Okay. Now the next one says:
(Reading) According to the Florida

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Attorney General's Office, clinics are often cash-only enterprises, employing doctors who write prescriptions for painkillers without examining patients (end of reading).
Do you see where it says that?
A. I do.
Q. And were you aware that was happening at pill mills?
A. It happens. Yes, it does.
Q. And would you characterize situations where that happens as a pill mill?
MR. DAVISON: Objection to form.
THE WITNESS: No, not necessarily. They could be. But it's certainly improper.
BY MS. HERZFELD:
Q. And could contribute to the diversion of opioids into the illegal drug market?
A. Absolutely yeah.
Q. And the next sentence there says:
(Reading) They have proved to be a magnet for buyers in the southeast, period. According to Frank Rapier, Director of the Appalachian High Intensity Drug Trafficking Area,

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Highway Patrol officers in hot spots, like eastern Tennessee routinely stop van loads of people returning from Florida with fresh stockpiles of prescription drugs (end of reading).
Did I read that correctly?
A. You did.
Q. And does this refresh your recollection at all about whether Tennessee was identified as a hot spot?
A. Yeah, a -- clearly what they are saying here, it is.
Q. And had you heard of the Appalachian High Intensity Drug Trafficking Area?
A. Never heard of it, no.
Q. And do you know who Frank Rapier is?
A. I do not.
Q. Have you ever had a conversation with him?
A. I have not.
Q. Okay. But you agree with this statement that Florida was a hot spot for those drugs to be brought up into the illegal drug market?
MR. DAVISON: Objection to form.
THE WITNESS: I do agree.

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BY MS. HERZFELD:
Q. Okay. And specifically into the illegal drug market in eastern Tennessee?
A. Yes.
MR. DAVISON: Objection to form.
THE WITNESS: That's what it says here. I have no basis to disagree with it.
BY MS. HERZFELD:
Q. Okay. And then in the next line it says:
(Reading) In West Virginia, state Senator Evans Jenkins -- Evan Jenkins said flights on discount airlines between Huntington, West Virginia and Fort Lauderdale, Florida have been dubbed the Oxycontin Express (end of reading).
And before I think we -- you had been asked if you had heard the term Oxycontin Express or Oxy Express. And I don't remember what you answer was?
A. I hadn't heard of it.
Q. And had you heard of I-75 being designated as the Oxy Express?
MR. DAVISON: Objection to form.
///

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BY MS. HERZFELD:
Q. Or highway?
A. I have not.
MS. HERZFELD: Okay. You can take this document and set it aside, please.
THE WITNESS: Are we done with this one?
MS. HERZFELD: Yes.
THE WITNESS: Oh, okay.
MS. HERZFELD: I'm going to hand you the next exhibit, which will be marked as Exhibit No. 24.
(Exhibit No. 24 was marked.)
MS. HERZFELD: Okay. For the record, this is MNK-T1, underscore --
A. I've got two of them.
MS. HERZFELD: Oh, you've got two. There you go. Underscore 0004298470, and it's a two-page document.
THE WITNESS: Uh-huh.
BY MS. HERZFELD:
Q. Okay. Sir --
A. I'm very familiar with this.
Q. Okay. What is it, sir?
A. So this is -- this is an agenda for a quarterly REMS Safety Board meeting. These occurred quarterly --

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Q. Okay.
A. -- with our panel of experts. We presented data for their review and feedback and action items that we would take and make into actionable plans.
Q. Okay. And if you will look here on the very first page, the speaker that's assigned from 9:35 a.m. to 9:50 a.m., is that you?
A. That's me.
Q. Okay. And did you indeed speak at this?
A. I did.
Q. Okay. And does this maybe refresh your recollection as to whether you've been to Tennessee for business?
A. I forgot about Nashville. I've been -- actually, I've been to Nashville many, many times. I just completely forgot about it.
Q. Oh, you have?
A. Yeah.
Q. You know, most people don't forget Nashville so easily.
A. I know. I'm really sorry, because I've been to Nashville maybe ten times, and I just blanked out.

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Q. That's okay. So why don't you tell me, other than this -- we will come back to this agenda in just a second.
A. Okay.
Q. But the other times that you've been to Nashville. Has that been for business or for personal?
A. Both. Mainly business. And when I worked for Cardinal Health, Cardinal Health had a big facility in Nashville.
Q. Okay.
A. It was a third-party logistics distributor company, and I used to go there, you know -- you know, a number of times.
Q. Okay. And so when you were working for Cardinal Health, and you would come to Nashville for that distribution issue or meetings, did any of that have to do with the diversion of opioids --
A. No.
Q. -- and prevention of diversion of opioids?
A. No.
Q. Okay. Okay. And so other than your time with Cardinal Health and other than personal times, other than this meeting that we just talked

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about, have you been to Nashville for business reasons for any other times?
A. Not that I can remember, no.
Q. Okay. And so let's go back to this meeting then --
A. Okay.
Q. -- that you had here on April 8th and 9th, 2011, at the Loews Hotel in Nashville; is that correct?
A. That's correct.
Q. Okay. And do you recall that Loews being across the street from Vanderbilt University?
A. I do.
MR. DAVISON: Objection.
THE WITNESS: Because I went running on the campus.
BY MS. HERZFELD:
Q. It's pretty, isn't it?
A. Yes. Very beautiful.
Q. Yes, very good. Okay.
Looking at this agenda, I see that it's you speaking, and then we have some other folks. So I just want to make sure I understand who they are.
I think there was already a discussion about Lynn Webster, so I don't think we need to ask about

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Lynn. That's the same Lynn Webster that was discussed earlier; is that correct?
A. Correct.
Q. Okay. And what Herbert Neuman, who is --
A. He's Chief Medical Officer of Covidien.
Q. Okay.
A. My direct supervisor.
Q. And so he would be a Covidien/Mallinckrodt employee; is that right?
A. Yes.
Q. Okay. And then Danielle Burroughs. Who is Danielle Burroughs?
A. Danielle was a pharmacist and worked in Pharmacovigilance at Mallinckrodt.
Q. And then Bobby Clark. Who is Bobby Clark?
A. Bobby Clark is an epidemiologist who was on my Patient and Product Safety Team.
Q. Okay. And not a Mallinckrodt employee?
A. Yes.
Q. Was a Mallinckrodt or was not?
A. He was. He was.

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Q. Okay. And Julie Milford. Who is Julie Milford?
A. I actually don't know.
Q. Okay.
A. Yeah.
Q. How about Jenny Wang, MBA?
A. Jenny Wang worked for me. She's on the Patient Product Safety Team.
Q. So she would have been a Mallinckrodt or Covidien employee?
A. She's a Mallinckrodt employee.
Q. Okay. I think that covers everybody that was on the list; does that sound correct?
A. It does.
Q. Okay. And so the people who attended this conference, would that have been just people that were on your advisory board, or would it have been open to other physicians or prescribers?
A. No. It was -- it was -- the purpose of the meeting was to present data on the use, side effects, reported problems, program success of the Exalgo REMS and Exalgo to these experts for their -- to give them an opportunity to weigh in on the data and give us their impressions of what was really happening behind the data. So they were interpreting

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the data.
Q. Okay. And who were the experts?
MR. DAVISON: Objection to form.
THE WITNESS: It was -- Debra Gordon was one. David Brushwood. I think I went through this before. Do you want me to tell you who they were or --
BY MS. HERZFELD:
Q. Is it the same list you went through before?
A. It was, yeah.
Q. Okay.
A. And there were others. I can't remember all of them, but there were a few more, yeah.
Q. Okay. And do you know if were any Tennessee prescribers that were there?
A. Oh, no, prescribers were not invited to the meeting.
Q. Okay. Do you know if there was anyone who was from Tennessee or based in Tennessee that was at the meeting?
A. At the time -- I don't know exactly, but at the time Steve Passik may have been an employee at Vanderbilt. I know at one time he was.

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But I don't know if at this particular time he was working at Vanderbilt.
MS. HERZFELD: Okay. You can set that aside.
THE WITNESS: Okay.
MS. HERZFELD: Thank you, sir.
I'm going to hand you what we will mark as collective Exhibit 25.
(Exhibit No. 25 was marked.)
MS. HERZFELD: For the record, I just handed Mr. Morelli what we have marked as Plaintiffs' Exhibit 25. The Bates number is MNK-T1, underscore, 0007901956.
It looks like I may have copied this email twice. So I don't know if you have got two pages or one. But it should be a one-page email with an attachment. And the attachment placeholder page is MNK-T1, underscore, 0007901957. So it's an email and an attachment.
Q. Okay. Mr. Morelli, if you will just take a look at the email for one second for me, please.
Okay. You see the email?
A. I do.
Q. Okay. And this is an email that was

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sent from Regina Ruben to you and it looks like a whole bunch of other people.
A. Right.
Q. On October 8th, 2009; is that correct?
A. That's correct.
Q. Okay. And do you have any reason to believe that you didn't receive this email in the ordinary course of your business?
A. No.
Q. Okay. So you believe that this email is something that you received?
A. I do.
Q. Okay. And so who is Regina Ruben?
A. Regina Ruben is -- was an employee of Paragon Rx, the coGnsulting firm we used to run everybody through the Rx FMEA process in terms of building safe use tools.
Q. Okay. And Jeremy Stamer, do you know who that is?
A. Jeremy Stamer is a Mallinckrodt employee. He's in the Prescription Data Analytics in Mallinckrodt.
Q. What does Prescription Data Analytics do?

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A. So data comes in through a data service, and it's quite voluminous, and people like Jeremy Stamer and his team would get inside the data and kind of translate raw data into kind of usable, actionable information, understandable information rather than a page full of numbers.
Q. Okay.
A. Yeah.
Q. Okay. And if you look at this email, it looks like Regina is forwarding something to you and a bunch of other folks --
A. Right.
Q. -- where it says:
(Reading) Attached is Jeremy Stamer's parameters from this morning's core team CT. Thanks, Regina (end of reading).
Did I read that correctly?
A. Yes.
Q. And do you know what she's referring to when she's talking about a core team TC?
MR. DAVISON: Objection to form.
THE WITNESS: I do not know what TC -- what the context in which she's using TC. Maybe it's core team backwards or something. I don't know.

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BY MS. HERZFELD:
Q. Teleconference, maybe?
A. It could be. I think it's a teleconference, yes. Core team teleconference. Because we did it verbally, and then he followed up with the hard copies. Yes, I think that's what it is.
Q. Okay. And core team would be which team? Is that the Covidien Exalgo REMS?
A. So let me just look at the "To" list.
So the "To" line on this cover memo -- oh, wait. So this is a laundry list of employees at Paragon Rx and employees at Covidien who were involved with the Rx FMEA process.
Q. Okay. Now, if you will flip with me to the -- this is the attached -- I will submit to you, this is the attachment we have printed out here, the PowerPoint.
And let's take a look at the first page, the title page here. It says, "Exalgo REMS," which I think we've talked about a lot already today, "A Commercial Analytics Perspective."
A. Right.
Q. What is a commercial analytics perspective?

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MR. DAVISON: Objection to form.
THE WITNESS: So in the process of operating the REMS, operationalizing the REMS, we need to collect data that tell us who's prescribing the product, how much product is being prescribed, where it's being prescribed, all those prescription data analytics. Because that data has to be presented to the Exalgo REMS safety board.
MS. HERZFELD: Okay.
THE WITNESS: And that's data we use to try to understand if the product is being used appropriately, at least from a data analytics perspective. And if there's any hot spots or things that look bad, we need to dig into that further.
BY MS. HERZFELD:
Q. Okay. Because that would be a responsible thing for Mallinckrodt to do?
A. Right.
Q. If you have that data, you want to dig into it further and find out if your product is being abused or misused or diverted; is that right?
MR. DAVISON: Objection to form.
THE WITNESS: That's exactly right.
BY MS. HERZFELD:
Q. The second page. "Market Overview,

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Data and Information Needs, and Implementation Strategy." Okay?
A. Yes.
Q. Flip to the next one. Okay. Then it talks about market overview. Do you know what's meant by "market overview"?
A. Market overview is how the company has segmented the market and where they are going to send sales reps.
Q. Okay.
A. So part of -- part of -- part of responsible -- responsible use is targeting the right physicians, not targeting physicians who have no reason by their specialty or by their practice to prescribe Exalgo. A sales rep can't be in that office because there's nothing good can come from that, because they are not seeing chronic pain patients.
Q. Okay.
A. At least on the surface.
Q. Okay. So it says, "Market Overview Prescribers." And then, "Targeting and Scope, introducing Dr. Mark Murphy." Then "Pharmacies, chains, independents, mail order, specialty and hospital."

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So does that -- generally does that match with your understanding of what the market was for Mallinckrodt-branded opioid product?
A. Yes.
Q. Okay. Next page it talks about market overview here and volume segmentation. Did I read that correctly?
A. Yes.
Q. Okay. And then it talks about these different product families, which I think you had already discussed earlier, so I won't spend a lot of time on that.
A. Okay.
Q. But suffice it to say, you've got oxycodone, morphine, fentanyl and Opana. Did I summarize that correctly?
A. Oxycontin, yeah.
Q. Okay.
A. Morphine products. Fentanyl products and Opana.
Q. And then it talks about a prescriber audience greater than 325,000 active prescribers. Do you know what that means?
A. That the -- the potential number of prescribers who would be the called-on audience could

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be as large as that. But -- and these are the metrics that we use to analyze that target market and to break that target market down into more sub targets, you might say.
Q. Okay. And when you say "called on," is that sometimes also being referred to as being detailed?
A. It is.
Q. Okay. And so then this breaks it down by various deciles. And it looks like there's ten different deciles; is that your understanding?
A. Yeah, that's -- deciles are always in tens, yeah.
Q. Okay. So if people that are decile ten for the prescriber, those would be the highest prescribers?
A. Right.
MR. DAVISON: Objection to form.
BY MS. HERZFELD:
Q. Okay. Next one:
(Reading) Segmenting Physicians by Product Use: Identifying physicians predisposed to prescribing one product, one product written 50 percent of the time or more (end of

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reading).
Did I read that correctly?
A. You did.
Q. Do you know what that means?
A. Yes. It was -- it was trying to create an understanding of which of those physicians were essentially using one product or were prescribing multiple products to their patient population.
Q. Okay. And when you --
A. It depends on their habits and their comfort level.
Q. Okay. And so when you're talking about products, is that opioid products or are you looking at every single prescription?
A. Oh, no, these are just long-acting opioids.
Q. Just long acting?
A. Not opioids, long-acting opioids.
Q. Long acting. Okay. Switch to the next one.
"Segmentation Survey." So looking at this one, there's among deciles ten to three, the spreader segment is the largest.
Do you know what that means?

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MR. DAVISON: Objection to form.
THE WITNESS: The spreader segment was a descriptor intended to identify -- that went with the segment that spread their use across product types, as you can see there --
MS. HERZFELD: Okay.
THE WITNESS: -- as opposed to have dominant of one or the other.
BY MS. HERZFELD:
Q. Okay. I see. So there's spreaders that you -- that will prescribe multiple opioids within their practice --
A. Right.
Q. -- and then there's other folks that were called more dominant groups, and they prefer one?
A. Right.
Q. And so then that would make sense for that second bullet which then says:
(Reading) Dominant groups: Oxycodone prescribers are the most loyal, with an average of 70 percent for Oxycontin (end of reading).
Is that your --
A. Yes.

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Q. And your understanding is that's accurate?
MR. DAVISON: Objection.
THE WITNESS: That's accurate.
BY MS. HERZFELD:
Q. Okay. Next page.
(Reading) Manually tuning the segmentation increases the overall coverage of the market without compromising the strategy (end of reading).
Do you have any understanding of what that means?
MR. DAVISON: Objection.
THE WITNESS: I just think it's saying that you have the raw data, and then it's tweaked somehow based on other criteria. But I don't recall this at all, quite frankly.
BY MS. HERZFELD:
Q. Okay. And when they're talking about coverage of the market, is it coverage of the market for sales?
MR. DAVISON: Objection to form.
THE WITNESS: Coverage of the market in terms of the -- the intensity of prescribing, which

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is very important to us.
MS. HERZFELD: Okay.
THE WITNESS: And it's very important from a safety perspective too.
BY MS. HERZFELD:
Q. Okay. Why?
A. Okay. So a high prescriber has the potential to do more harm than a low prescriber.
Q. Okay.
A. So if I'm designing a safety program, I'm going to focus -- first step out the door, I'm going to focus on the highest prescribers of Exalgo, because they have the potential to harm more patients than someone who writes one prescription and doesn't write another prescription for six months.
It could take a lot of energy and time and money to get that physician that's in West Bemidji, Minnesota to fill out the EEIF and read the REMS. And when we go there, he says, I wrote one prescription for Exalgo. I'm never writing another.
I'd rather go to Freddie Smith over here in Indiana, who writes ten prescriptions a week, and put my energy in on him in terms of education.
Q. Okay.
A. So it's -- it's a reflex -- it's a

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reflex based on what their prescribing activity is.
Q. Okay.
A. Does that make sense?
Q. It does.
Moving forward. So then you have the next one, which is this very colorful chart here. And that's what that's talking about here --
A. Yes.
Q. -- right, the various deciles of prescribers and what they tend to prescribe; is that right?
A. It is.
MR. DAVISON: Objection to form.
BY MS. HERZFELD:
Q. Okay. And then switching to the next page, "Sales Force Sizing."
Were you involved at all in determining the sizes of the sales force?
A. No.
Q. Did anybody ever consult with you about sizes of the sales force?
A. No.
Q. Okay. Switching to the next one. Then it says, "Profile of a Target: Introducing Dr. Murphy."

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Do you know what a target is in this context?
THE VIDEOGRAPHER: Counsel, your paper is hitting your mic. Do you mind moving it up a bit.
MR. DAVISON: Sorry.
THE WITNESS: So this -- this is a profile of a prescriber. It's an illustrative profile of a prescriber and what that prescriber's prescription activity is.
BY MS. HERZFELD:
Q. Okay. And when it says "a target," does that mean a sales target for Exalgo?
A. A sales target.
Q. Okay. You're ahead of me. I was on this one. So I will switch to this one. Same page. Now we're on the same page.
At the top it says, "Dr. Mark Murphy," and then the prescriber ME, and a number. Do you know what a prescriber ME is?
A. Medical education number.
Q. Okay. Is that a license number?
A. It's a designation that physicians have that can be tracked. So it's a way to track them.
Q. Okay. And then here it says, "Market

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decile 10"; is that right?
A. That's right.
Q. And that's the highest decile for Mallinckrodt rankings; is that right?
A. That's right.
Q. And so what does that mean?
MR. DAVISON: Objection.
THE WITNESS: He's in the top -- he's in a group of physicians who collectively prescribe -- let me get this right -- ten percent of the -- the highest prescribers in the top ten percent of prescriptions.
So, in other words, there's -- so there's -- just make up a number 5,000 prescriptions. How many doctors does it take to generate 5,000 prescriptions. Well, the top ten percent, it only takes 32 of them. The next decile may take 50, and the next, 250. So the populations get bigger in each decile as you go down.
BY MS. HERZFELD:
Q. So if I understand your testimony, so this Dr. Mark Murphy would be in the group of the highest prescribers of long-acting opioids?
A. The highest, yes.
Q. Okay. And so if I understood you

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correctly before, that means he is at the highest possibility of doing the most harm?
MR. DAVISON: Objection to form.
THE WITNESS: Correct.
MS. HERZFELD: Okay. Okay.
THE WITNESS: That's how I look at it. The sales guys look at it as this is the most -- place where we can get the most prescriptions, because they already believe in long-acting opioids, they have the patients for long-acting opioids.
I look at it the flipside. I look at it, you're right. That's why I have to get this Exalgo REMS information and the Exalgo C.A.R.E.S. Alliance information in there.
BY MS. HERZFELD:
Q. Okay. Okay. And then it says that this -- this doctor's practice location is the North Alabama Pain Services in Decatur, Alabama.
Do you know anything about the North Alabama Pain Services in Decatur, Alabama?
A. No.
MR. DAVISON: Objection.
BY MS. HERZFELD:
Q. Okay. Switching to the next one. Is this what you were talking about for specialty, it

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makes a difference for you?
A. Yes.
Q. Okay. And so what is Dr. Mark Murphy's specialty, according to this chart?
A. Anesthesiology.
Q. And is anesthesiology the type of practice you would expect to see a high prescribing of opioids?
A. If they practice pain management. Not all anesthesiologists practice pain management. Some practice in the hospital, and they give anesthesia during surgery. They would not be a target.
But an anesthesiology, the other part of anesthesia is they become a pain specialist and treat patients with chronic pain.
Q. Okay. Switching to the next one. And it talks about pharmacies. Do you know what this chart -- or what this -- what this slide represents here?
MR. DAVISON: Objection.
BY MS. HERZFELD:
Q. Let me back up.
A. Yeah.
Q. Do you know if Mallinckrodt was also

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looking at where a particular physician's prescriptions were filled --
A. Yes.
Q. -- when making sales determinations?
A. Yes. Yes.
Q. Okay. And so in this case it looks like, when profiling Dr. Mark Murphy, there's a discussion about chain pharmacies, independent pharmacies, mail order pharmacies, et cetera; is that right?
MR. DAVISON: Objection to form.
THE WITNESS: I believe so. I can't be sure whether it's Mark Murphy or whether it's pharmacies and chains in general. I can't tell from this.
BY MS. HERZFELD:
Q. Okay. But, to your understanding, Mallinckrodt did track where it is that various physicians' prescriptions for Exalgo were being filled?
A. Right. Because if -- yes, they did. They did.
Q. Okay. And do you know why they tracked that information?
A. Sure. Because if a physician in Decatur, Alabama, and there's -- let's say there's

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one main pharmacy in Decatur, Alabama, writes a script for Exalgo, and the patient takes it to the Decatur, Alabama pharmacy and they don't have Exalgo, that patient is extremely unhappy. Because, remember, that patient is in pain.
Q. Right.
A. So that patient is going back to the doctor with a big complaint.
Q. What about for the patients who actually aren't in pain, that are just trying to get the drugs from the doctors?
MR. DAVISON: Objection to form.
THE WITNESS: They can't get the drugs from the doctors. They can get a prescription from the doctors. They can't get the drugs from the doctors.
BY MS. HERZFELD:
Q. They can get the drugs from the pharmacies with a prescription written by the doctor; is that correct?
A. That's correct. Our focus was on proper prescribing. That's the faucet that goes open or closed.
Q. Okay. Then if you switch to the one that says, "REMS Metrics and Tracks Data." Do you see that?

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A. Right. Right.
Q. It talks about enrollment. Do you know what they were talking about here with enrollment?
MR. DAVISON: Objection to form.
THE WITNESS: I believe it's enrollment in the REMS, the Exalgo REMS.
BY MS. HERZFELD:
Q. So is that the filling out the sheet thing you talked about earlier?
A. The EEIF, yeah.
Q. Okay. Is there anything more than the EEIF?
A. There's more, but it's -- so we -- what can we track? We can track the EEIF because we have it. We can track their prescription activity because we have it.
Q. Okay.
A. And then we justify those two against each other. And if we have a prescriber that doesn't have an EEIF, you send people in there.
Q. Okay.
A. Yeah.
Q. Okay. So then we will just flip all the way here to the end, "The Strategic Approach REMS

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Implementation." And then there's this chart on the very last page. Do you see the chart?
A. Uh-huh.
Q. It's a very colorful chart?
A. Thank you.
Q. So I want to make sure -- did you create this chart?
A. Oh, God, no.
Q. I wanted to just make sure that I understand it. So this goes -- we have the physician, and then it says "Rx."
The physician writes the prescription to the patient; is that right?
A. Yes.
Q. Okay. And then the patient -- there's an arrow that goes to the pharmacy with Rx. So does that mean fills the prescription?
A. Fills the prescription at a pharmacy.
Q. And then there's an arrow going the other way with the pills?
A. The pills go back to the patient.
Q. Okay. And then it has the manufacturer sends the pills to the pharmacies. Do you see that?
A. It leaves out a step there, because

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it goes to the wholesaler first. But effectively it goes to the pharmacy.
Q. Okay. And then on here, between the pharmacy and the physician, there's a thing called database. What's the database; do you know?
A. The database is a representation of all the data analytics that go on. It's not really a box or a single thing. It's a global kind of thing.
Q. Okay. And so it talks about eligibility of prescriber and patient?
A. Right.
Q. Do you know what that is?
A. That's the EEIF on -- on file for that prescriber.
Q. Okay.
A. And --
Q. And then going the other way from pharmacy to database, it says, "Enroll pharmacy." Do you know what that is?
A. That, I believe, is a pharmacy that reports -- reports data. Not all pharmacies do. But today nearly all do.
Q. Okay.
A. Very high.
Q. And then all the way at the bottom

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there's an arrow going from database to manufacturer, and it says, "Eligibility of Pharmacy." Do you know what that is?
MR. DAVISON: Objection to form.
THE WITNESS: That's a way for us to check whether we're sending drugs indirectly, because we're sending it through a number of steps, but ultimately its destination is an eligible pharmacy, a real pharmacy, a legitimate pharmacy.
BY MS. HERZFELD:
Q. Because you would want to make sure --
A. Right.
Q. -- that your drugs aren't getting to an illegitimate pharmacy?
A. Right.
Q. And would you want to make sure that your opioids aren't getting to doctors who are prescribing them for inappropriate purposes?
A. Exactly.
MR. DAVISON: Objection to form.
BY MS. HERZFELD:
Q. And you want to make sure that your opioids aren't getting into an illegal drug market where they are being abused?

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MR. DAVISON: Objection to form.
THE WITNESS: Absolutely.
BY MS. HERZFELD:
Q. Do you know anything about Dr. Mark Murphy?
A. No, nothing.
Q. Do you know if Dr. Mark Murphy still has a medical license now in Alabama?
A. I have no idea.
MR. DAVISON: Objection.
THE WITNESS: I don't know if he was a real doctor. It may have been made up just to illustrate a point. I really don't know. This is an educational setting, so it may not be real.
BY MS. HERZFELD:
Q. So if Mark Murphy was real, do you know if he ever filled out the REMS --
A. I have no idea.
MR. DAVISON: Objection to form.
MS. HERZFELD: What's the objection?
MR. DAVISON: You're asking him to speculate. He just told you he never heard the name before.
MS. HERZFELD: I guess it's a good point.
Q. What would happen if you asked a

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physician to fill out the REMS survey and they didn't?
A. What would happen or could happen?
Q. Yes.
A. A variety of things.
Q. Okay.
A. You know, I can give you a spectrum of kind of the responses that we got. But that's -- that's what you're looking for?
Q. Sure.
A. Some would do it instantly.
Q. Yep.
A. Some would want to understand why they are doing it. Some would say, come back another day, and I'll do it. Some would say, I'm never going to do this. Any others like that, you know, in that neighborhood, yeah.
Q. And so if someone was like, I'm never going to do it or they came up with a million excuses to never really turn it in, was that information that you would collect?
A. Oh, absolutely.
Q. And is that information that you would turn over to other folks at Mallinckrodt?
A. Perhaps eventually. But we would

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make multiple efforts to reason with the individual physician. Or to get his staff to help do it often works. You have to be crafty.

Q. Do you think it could be suspicious if a -- if a physician didn't want to share that information?

MR. DAVISON: Objection to form.

THE WITNESS: It could be. It could be the -- that the physician -- it's more than likely the physician is suspicious about signing anything that goes to a pharmaceutical company, you know.

BY MS. HERZFELD:

Q. Couldn't it also be that the physician doesn't want to share information about their prescribing habits because perhaps they are not legitimate?

MR. DAVISON: Objection to form.

THE WITNESS: It could be. But we have their prescribing habits without or without the EEIF. We don't need the EEIF to get them. And they probably know that. But it's amazing, some don't know.

BY MS. HERZFELD:

Q. During your time at Mallinckrodt, did you ever identify any prescribers that you suspected

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were prescribing for illegitimate purposes?

A. I didn't. But we had multiple instances of such kind of activity that we, you know, flagged certain prescribers based on their prescription activity, and sent in health-care professionals to try to investigate not only their prescribing activity, but adverse event occurrences, where that -- the physician was -- you know, the physician relevant to the patient that has a severe adverse event.

Q. Okay. And who would have been responsible for that at Mallinckrodt?

A. For going into the doctor's office?

Q. Yes, sir.

A. Usually Eddie Darton, who is a physician, or one of our Pharm.Ds, depending upon the severity and the location.

Q. Okay. So I'm going to kind of then shift just a little bit, because I want to make sure that I understand it.

If I understood your testimony earlier, you were talking about training of salespeople to detect signs of diversion.

A. Uh-huh.

Q. Do I remember that correctly?

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A. No, not to detect signs of diversion, because they wouldn't really have that opportunity except if it's a pill mill. We train them to detect pill mills, which is something you can do visually from the parking lot.

Q. Okay. And who was responsible for that training?

A. Medical Affairs.

Q. So that would have been in your purview?

A. More -- more the health-care professionals and I would cooperate on it, yeah.

Q. Okay. And was there -- was there a program on training them?

A. There was a complete training program, yes, with videos and examples and pictures and things, yeah.

Q. Okay. So if I went to look in Mallinckrodt's documents, I could find that somewhere, a packet?

A. I'm sure you could.

Q. Do you know what it was called?

A. No.

Q. Okay. And so contained with that, in the training of the salespeople to spot pill mills,

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we will call it that, if you're more comfortable with that, do you know who specifically did the training on that?

A. I think we -- I did a lot of the rep training on REMS and C.A.R.E.S. Alliance. So it's more than likely I did some of it. But there was follow-up from others in Medical Affairs.

Q. Okay. And do you know who created that program, where it came from?

A. The training?

Q. Yes, sir.

A. We did. We did, yeah.

Q. And do you know who Karen Harper is?

A. I know the name. I don't know her personally.

Q. Did you consult with anyone on the generic side of Mallinckrodt in developing those signs to look for?

A. No, we did not.

Q. Where did you get the information that you trained folks on, on how to spot pill mills?

A. Just from data, literature, personal experience, recommendations of experts. It's a compilation of things, yeah.

Q. And would those salespeople be

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trained just when they started or were there periodic trainings?
A. Both. It's heavy when they start, and then there's follow-up. Training never stops in pharmaceuticals because things change.
Q. Okay. And what was your sales force instructed to do if they thought they had spotted signs that there was a pill mill?
A. Don't go in there. Don't have anything to do with them. And report it to us.
Q. Okay. And what types of things were they trained to look for?
MR. DAVISON: Objection to form.
THE WITNESS: A doctor's office next door or contiguously constructed with a pharmacy. Long lines of patients outside the door of the physician's office. Patients spending five minutes or less in the physician's office, coming out and going next door to the pharmacy, filling a prescription and getting -- getting in their car, driving away. A large number of out-of-state license plates --
THE VIDEOGRAPHER: Is your phone buzzing?
THE WITNESS: I'm sorry. I thought I turned it off.
Long lines of out-of-state license plates on

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cars. Those types of things.
BY MS. HERZFELD:
Q. Okay. And so when you said they should report it, who would they report it to?
A. Generally to their management first. That would get kicked up line and eventually would end up at us, Medical Affairs.
Q. Okay. And what -- what type of actions would be taken at Medical Affairs, if there was such a report?
A. First is avoidance, so that we wouldn't have anything to do with it. Make sure that we weren't selling product into those pharmacies, we weren't interacting with those physicians.
And I'm not sure how often it bubbled up to reporting them to the medical Board. But I know at other companies that I consulted with on this same kind of issue that had opioids, we reported them to the Medical Board. I can't remember if that happened at Covidien or not.
Q. And what about reports to the DEA while you were at Covidien, do you know if those occurred?
A. I don't -- I don't know.
Q. What about reports to Tennessee law

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enforcement, do you know if that occurred?
A. I do not know.
Q. Do you recall any events of anybody reporting suspected pill mills or signs of diversion in Tennessee during your time at Covidien?
A. I do not, no.
Q. Did Mallinckrodt have a "Do Not Call" list?
A. They did.
Q. Okay. And do you know if any physicians from Tennessee were on that list?
A. I do not know that.
Q. Okay. Do you know how many physicians, approximately, were on that list?
A. Without being named specifically, there was a huge "Do Not Call" segment of the prescribing -- potential prescribing population because they didn't meet the standards that we set for their specialty or their patient population. So there was no justification for having a sales rep in there.
Q. Okay. So mostly you -- you folks spent your time on the physicians that were prescribing the highest level of long-acting opioids?
MR. DAVISON: Objection to form.

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THE WITNESS: And -- not just that. And had the right training.
So you're starting out with a select group that's kind of automatic risk mitigation, because these are pain experts as opposed to some doctor who hasn't had the training, who is just a high prescriber. That's a danger. That's a danger sign.
BY MS. HERZFELD:
Q. So high prescribers of long-acting opioids who had a specialty like pain management?
A. Anesthesia, pain management, et cetera, yeah.
Q. And that's where most of the focus was for sales?
A. Right.
MS. HERZFELD: Okay. I think I understand that now. I've just got a little bit more for you. My battery is going to run out.
We will mark this next one as Plaintiffs' Exhibit 26.
(Exhibit No. 26 was marked.)
BY MS. HERZFELD:
Q. I only have just a couple questions more, so it might be easier if I just ask you the questions first.

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A. Okay.
Q. We will get you out of here a little faster.
A. Okay.
Q. For the record, Exhibit 26 is Bates No. MNK-T1, underscore, 0006314936, which is the attachment that is -4937.
Okay. If you will take a look at the first page, which is the email, for me, sir.
A. Yes, I have it.
Q. Okay. And this appears to be an email that is sent from Preston Walker on -- to a bunch of folks, and then copies Bobby Clark and you; is that correct?
A. That's correct.
Q. Okay. And it's dated 2-14-2011; is that correct?
A. That's correct.
Q. Okay. And do you have any reason to -- do you believe that you received this email in the regular course of your business?
A. I do.
Q. Okay. So it says here, "PPF." I think you said what that meant earlier?
A. Patient Product Safety Team.

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Q. Okay. (Reading) Bobby and I were asked to put together an upcoming advanced sales training. Please review the attached presentation and return comments to me by COB on Tuesday, 2-15-11. Thanks, Preston (end of reading).
Did I read that correctly?
A. You did.
Q. Now, let's just flip through this thing here.
Okay. If you will look at slide No. 9, at page No. 9. Did you create this document, sir?
A. I did not. I reviewed it. I participated in creating it, but I didn't actually physically create it.
Q. Okay. If you will read for me what it says on slide 9 here.
A. (Reading) federal law enforcement authorities in November 2009 dismantled the Florida drug trafficking ring that had sent more than 100,000 oxycodone tablets from South Florida pain clinics to abusers in Kentucky and North Carolina,

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Tennessee, Virginia, and West Virginia. At least 20 people were indicted on distribution charges. The ring had allegedly operated for three years and used at least four or five clinic doctors per day -- per day to obtain the drugs. Members of the ring shipped thousands of pills every day by vehicle or overnight delivery services and allegedly made at least $5 million over three years (end of reading).
Q. And the citation for that is the National Drug Treatment Assessment --
A. Right.
Q. -- is that correct?
A. That is correct.
Q. Do you know who the National Drug Treatment Assessment is?
A. It's --
Q. Or what it is?
A. Not exactly. But it's a national kind of initiative to address this problem.
Q. Okay. You consider it to be a reliable source?

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A. I don't know. I can't comment on that. But I'm assuming it would be.
Q. Do you have any reason to doubt what you just read --
A. Oh, no. No, I have no reason to doubt it.
Q. So in this case, the information that you just read talks about federal law enforcement arresting people for engaging in a conspiracy to sell 190,000 oxycodone tablets; is that correct?
MR. DAVISON: Objection to form.
THE WITNESS: That's correct.
BY MS. HERZFELD:
Q. Okay. And it says that those were coming from South Florida pain clinics to abusers in Kentucky, North Carolina, and Tennessee; is that right?
A. That's correct.
Q. And Virginia and West Virginia, just to be complete?
A. Yes.
Q. Does that indicate to you that oxycodone were going from South Florida pain clinics into the illegal drug market in Tennessee?
A. Absolutely.

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Q. Okay. And it says:
(Reading) At least 20 people were indicted. The ring operated for three years and used at least four or five pain clinic doctors per day to obtain the drugs (end of reading).
Is that right?
A. Yes.
Q. Okay. And then it was talking -- before it was talking about pain clinics; is that right?
A. Yes.
Q. So in this situation you had people, doctors, who were pain management doctors at pain clinics; is that right?
MR. DAVISON: Objection to form.
THE WITNESS: As I understand it, these were -- this is -- this is basically the pill mill practice.
BY MS. HERZFELD:
Q. Okay. So I guess my question is, if you're talking about targeting folks for sales that are high prescribers of long-acting opioids who are also an appropriate -- an appropriate specialty, like pain management, that could be a pill mill, they

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could be operating a pill mill or it could be legitimate; is that right?
A. Absolutely.
MR. DAVISON: Objection.
BY MS. HERZFELD:
Q. Okay. And when you're targeting them, do you know if they are a pill mill or a legitimate operation?
A. Not -- not initially.
MR. DAVISON: Objection.
THE WITNESS: We need to do more due diligence to find that out, to verify that where they are going is legitimate. And the reps are trained for telltale signs, that as I talked about before.
BY MS. HERZFELD:
Q. Okay. And what would happen if a rep saw those signs and didn't report it?
MR. DAVISON: Objection to form.
THE WITNESS: And didn't report it. And then it was discovered later; is that what you mean?
MS. HERZFELD: Yes.
THE WITNESS: They'd be in a lot of trouble.
MS. HERZFELD: Okay. You can set this one aside.
I have got one more, one more real quick.

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And so if it looks like you need to stop, just let me know. Okay?
THE VIDEOGRAPHER: Okay.
MS. HERZFELD: Okay. Exhibit 27. No. 27 -- it's actually 27 and 28. So let's mark them at the same time, if that's okay, because they kind of go together. We will just do 27 first.
(Exhibit No. 27 was marked.)
MS. HERZFELD: I have handed you what we have marked as Exhibit 27, which is an email Bates No. MNK-T1, underscore, 0007094004, and it is a three-page email, a three-page email chain.
Q. Sir, is this an email that was sent to you from Kevin Lenaburg on June 8th, 2011?
A. Yes.
Q. Okay. And did you receive this email in the ordinary course of your business?
A. I assume I did, yes.
Q. Okay. And so my question about this is actually pretty -- pretty easy. If you will just set this down for a second, and then we can talk about it in a minute.
Do you know the book called "Defeat Chronic Pain Now!"?
A. I do.

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Q. Have you ever read the book?
A. I've read parts of it. I have perused it. I haven't read it word for word.
Q. Okay. And did the C.A.R.E.S. Alliance provide copies of "Defeat Chronic Pain Now!" to prescribing physicians?
A. We did, amongst other books, yes.
Q. Okay. What other books did you prescribe -- did you provide?
A. Dr. Fischman's book on "Risk Management." I think those are the two main ones that we did, yeah.
Q. Okay. And other than prescribing physicians, did "Defeat Chronic Pain Now!" go to other folks as well?
A. "Defeat Chronic Pain Now!" was a book that we gave to physicians to give to their patients.
Q. Okay. And I should have asked you before. This is just an aside, and I'm sorry to kind of go off a little bit.
When we were talking about detailing of physicians, to your knowledge, did Mallinckrodt sales folks also detail pharmacies?
A. I don't know, really.
Q. Okay. Did you ever hear about,

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perhaps, Mallinckrodt detailing pharmacies to make sure that they had Exalgo on their shelves in case a physician wrote a prescription?
A. I believe that --
MR. DAVISON: Objection to form.
THE WITNESS: I believe that happened, yeah.
MS. HERZFELD: Okay.
THE WITNESS: Initially, that's kind of up front at the launch. But once it's done, you don't have to go back anymore.
BY MS. HERZFELD:
Q. And did you have responsibility for training sales folks to detail pharmacies?
A. I did not, no.
Q. Do you know who would have?
A. The Sales Training Department. Yeah.
Q. Okay. So we don't need to look at this email, if you know that you already provided "Defeat Chronic Pain Now!".
A. Okay.
Q. Looking at "Defeat Chronic Pain Now!", it -- have you gone back and read "Defeat Chronic Pain Now!" since you left Mallinckrodt?
A. No.
MR. DAVISON: Objection to form.

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BY MS. HERZFELD:
Q. Okay. Do you know if any of the claims in "Defeat Chronic Pain Now!" have been disproven?
A. I do not know that.
Q. They talk about pseudoaddiction in "Defeat Chronic Pain Now!"; do you recall that?
A. I do recall that. Because pseudoaddiction is an issue.
Q. And what do you mean, it's an issue?
A. I mean it's a concern that people have, how to deal with people presenting with pseudoaddiction.
Q. And do you believe pseudoaddiction to be a legitimate scientific --
A. I'm not the one to judge that. But enough physicians tell me it's an issue -- or told me at the time. I don't talk about it now. But told me at the time it's something that they have to deal with.
Q. Do you know if that's true?
A. I really don't know if it's true.
MR. DAVISON: Objection.
BY MS. HERZFELD:
Q. Do you know if pseudoaddiction

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actually exists?
MR. DAVISON: Objection.
THE WITNESS: I do not.
BY MS. HERZFELD:
Q. Okay. Did the FDA approve the label for -- did the FDA approved label for Exalgo mention anything about pseudoaddiction, to your knowledge?
A. My -- my belief is they did not.
Q. Okay. And do you know if "Defeat Chronic Pain Now!" is available online?
A. I don't know.
MS. GAFFNEY: I don't think I have anymore questions. Thank you very much, sir.
THE WITNESS: You're welcome.
MR. DAVISON: Go off the record.
THE VIDEOGRAPHER: We are going off the record. The time is 6:58 p m.
(Recess taken.)
THE VIDEOGRAPHER: We are back on the record. The time is 7:02 p m.
EXAMINATION
BY MR. DAVISON:
Q. Mr. Morelli, thank you for your time so far. I just have a couple of questions for you.
A. Okay.

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Q. What was your role on the Suspicious Order Monitoring Team?
A. My role was to inform them of what the Patient and Product Safety Team was doing in terms of the REMS -- Exalgo REMS and the C.A.R.E.S. Alliance, to make them aware of what they were doing.
Q. Did you have any involvement with suspicious order monitoring of generic opioids?
A. I did not.
Q. Did you have any knowledge or understanding of how the suspicious order monitoring program for generic opioids worked at Mallinckrodt?
A. Not really.
Q. What was the goal of the sales force at Mallinckrodt?
A. To visit with prescribing physicians and their target audience and inform them of the risks and benefits of their promoted products.
Q. During your time at Mallinckrodt, did you have any role in charge-backs?
A. I did not.
Q. And do you have any understanding of how charge-backs worked at Mallinckrodt?
A. I do not.
MR. DAVISON: Thanks. Nothing further.

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FURTHER EXAMINATION

BY MR. SAMSON:

Q. You just were asked a question about the sales force's task at Mallinckrodt. Do you recall that?

A. Just now?

Q. Yes.

A. Yeah.

Q. And that they were to mix with doctors and give them risks and benefits; correct?

A. Correct.

Q. Did you have any role in following up to see if the sales force stuck to that assigned task or expanded their discussions with doctors?

A. No. But others did.

Q. Who?

A. The sales organization. The Legal Department. Medical Affairs, other than me, and et cetera.

MR. SAMSON: Okay. Nothing further.

MR. DAVISON: Thank you. I have nothing further.

THE WITNESS: Thank you.

THE VIDEOGRAPHER: This concludes the video deposition of Art Morelli. We are going off the record at 7:04 p m.

(The deposition was concluded at 7:04 p.m.)

--o0o--

Please be advised I have read the foregoing deposition, and I state there are:

(Check one) _____NO CORRECTIONS

_____CORRECTIONS PER ATTACHED

_____

ARTHUR F. MORELLI

DEPONENT'S CHANGES OR CORRECTIONS

Note: If you are adding to your testimony, print the exact words you want to add. If you are deleting from your testimony, print the exact words you want to delete. Specify with "Add" or "Delete" and sign this form.

DEPOSITION OF: ARTHUR F. MORELLI

CASE: IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION

DATE OF DEPOSITION: JANUARY 17, 2019

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CERTIFICATE OF REPORTER

I, SANDRA BUNCH VANDER POL, a Certified Shorthand Reporter, hereby certify that the witness in the foregoing deposition was by me duly sworn to tell the truth, the whole truth and nothing but the truth in the within-entitled cause;

That said deposition was taken down in shorthand by me, a disinterested person, at the time and place therein stated, and that the testimony of the said witness was thereafter reduced to typewriting, by computer, under my direction and supervision;

That before completion of the deposition, review of the transcript was requested. If requested, any changes made by the deponent (and provided to the reporter) during the period allowed are appended hereto.

I further certify that I am not of counsel or attorney for either or any of the parties to the said deposition, nor in any way interested in the event of this cause, and that I am not related to any of the parties thereto.

DATED: JANUARY 21, 2019

_____

SANDRA BUNCH VANDER POL, CSR 3032